Supreme Court, U.S.
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No. 10-125

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IN THE

Supreme Court of the United States

NATIONAL UROLOGICAL GROUP, INC., ET AL.,
Petitioners,

v.

FEDERAL TRADE COMMISSION,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1) Whether the decision below violated Petitioners' right to commercial free speech by applying standards and imposing restrictions on ingredient specific advertising that are more restrictive than necessary.

2) Whether the decision below effectively imposed a new standard for dietary supplement products, in contrast to the requirements of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), by requiring a dietary supplement producer to have clinical studies of its products prior to advertising such products.

3) Whether the decision below established a new standard for factual questions in cases alleging false advertising when it resolved, as a matter of law, that Petitioners' advertising was false and unsubstantiated, rather than allowing Petitioners to present their evidence to a trier of fact.

PARTIES TO THE PROCEEDING

Pursuant to Rule 14.1(b), the following list identifies all of the parties appearing here and before the United States Court of Appeals for the Eleventh Circuit.

The petitioners here and appellants below are National Urological Group, Inc., Hi-Tech Pharmaceuticals, Inc., Jared Robert Wheat, Thomasz Holda, Stephen Smith, and Terrill Mark Wright, M.D.

The respondent here and appellee below is the Federal Trade Commission.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6, Petitioners state that there are no parent corporations or publicly held corporations that own 10% or more of the stock of National Urological Group, Inc. or Hi-Tech Pharmaceuticals, Inc.

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Petitioners respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eleventh Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App. 1a)[1] is reported at 356 Fed. App'x 358 (11th Cir. 2009). The opinion of the district court (App. 3a-87a) is reported at 645 F. Supp. 2d 1167 (N.D. Ga. 2009).

JURISDICTION

The court of appeals denied the petition for rehearing and rehearing *en banc* on April 26, 2010.

This petition is timely filed within 90 days of that decision. Petitioner invokes jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS

This case involves the First Amendment to the United States Constitution and provisions of the Federal Trade Commission Act, 15 U.S.C. §§ 45(a), 52 and 53(b). In addition, this case implicates the provisions of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. 321, *et seq.* The relevant statutory provisions are reprinted at App. 90a-93a.

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[1] References to App. are to the appendix to the petition.

STATEMENT OF THE CASE

I. The FTC Act.

The Federal Trade Commission ("FTC") is an independent agency of the United States Government created by statute. The FTC enforces the Federal Trade Commission Act (the "Act"), which prohibits unfair or deceptive acts or practices in or affecting commerce. 15 U.S.C. § 45(a). In addition, the Act prohibits false advertising for food, drugs, devices, services, or cosmetics in or affecting commerce. 15 U.S.C. § 52. With respect to such advertising, FTC regulations require that advertisements be (1) truthful and not misleading and (2) supported by adequate substantiation for product claims prior to dissemination.

According to the FTC, to be adequately substantiated, advertisements related to a health benefit must be based upon "competent and reliable scientific evidence." *See FTC publication, Dietary Supplements: An Advertising Guide for Industry* (2001) at 9. The FTC has defined "competent and reliable scientific evidence" as "tests, analyses, research, studies, or other evidence based upon the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results" that support the specific claims made in the advertising. *Id.; see, e.g., In re Schering Corp.*, 118 F.T.C. 1030, 1127 (1994) (consent order).

II. DSHEA.

The Federal Food, Drug and Cosmetic Act (the "FFDCA") grants the Food and Drug Administration ("FDA") the authority to regulate, among other items, "drugs." Under the FFDCA, "drugs" are defined as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(B)(C).

In 1994, Congress amended the FFDCA by enacting the Dietary Supplement Health and Education Act ("DSHEA"),[2] which established a new regulatory category for dietary supplements. Congress enacted DSHEA to provide consumers greater access to and more information about dietary supplement products and to reduce governmental regulation. *See Nutritional Health Alliance v. Shalala*, 144 F.3d 220, 224 (2d Cir. 1998) (with DSHEA, Congress moved to "narrow the reach of the FDA's preauthorization scheme 'out of concern over excessive regulation of dietary supplements and the suppression of truthful information'").

In contrast to "drugs," under DSHEA "dietary supplements" are defined as:

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[2] Pub. L. No. 103-417, 108 Stat. 4325 (1994).

> [A] product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D) or (E).

21 U.S.C. § 321(ff)(1). Under DSHEA, dietary supplements are regulated as a subset of foods, rather than drugs. *Id.*[3] Unlike drugs, dietary supplements are *legally presumed* to be safe under DSHEA. *See* 21 U.S.C. § 342(f)(1)(A) (dietary supplements cannot be removed from the marketplace without the FDA first proving adulteration). As a result, dietary supplement manufacturers are not required to submit their products to pre-market clinical testing and scientific review for safety or efficacy. *See* 21 U.S.C. §§ 331(v) and 350b(c) (recognizing as lawfully marketable every dietary ingredient marketed in the United States prior to the effective date of DSHEA, October 14, 1994).

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[3] Section 321(ff) provides that "[e]xcept for purposes of 201(g) [the definition of a drug], a dietary supplement shall be deemed to be a food within the meaning of this Act."

In addition, dietary supplement manufacturers are permitted to place certain types of claims on their products without prior FDA approval. 21 U.S.C. § 343(r)(6). Specifically, DSHEA allows the manufacturer to include the following claims: (1) statements asserting "a benefit related to a classical nutrient deficiency disease and disclos[ing] the prevalence of such disease in the United States"; (2) statements commonly known as "structure-function claims" that "describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans [and] to characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function"; and (3) declarations of "general well-being from consumption of a nutrient or dietary ingredient." 21 U.S.C. § 343(r)(6)(A). These type of claims are permissible under DSHEA if the manufacturer has "substantiation" that the "statement is truthful and not misleading" and the label contains the following disclaimer in boldface type: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." 21 U.S.C. § 343(r)(6)(B), (C).

III. Procedural and Factual History.

In this case, the FTC brought litigation pursuant to § 13(b) of the FTC Act, 15 U.S.C. § 53(b), to secure injunctive and other equitable relief against National Urological Group, Inc., Hi-Tech Pharmaceuticals, Inc., Jared Robert Wheat, Thomasz Holda, Stephen Smith, and Terrill Mark

Wright, M.D. ("Petitioners"). According to the FTC, between 2001 and 2003, Petitioners made false and deceptive representations in the marketing and advertisement of two weight loss dietary supplement products – Thermalean® and Lipodrene® – and a sexual enhancement product – Spontane-ES®.

The FTC asserted that Petitioners' advertisements were false and not supported by adequate substantiation, in violation of § 5 of the Act, 15 U.S.C. § 45(a), and § 12 of the Act, 15 U.S.C. § 52. In making its allegations, the FTC acknowledged that it did not contend that any individual statement in the advertisement was not 100% accurate. Instead, the FTC contended that its claims were derived from the overall net impressions created by the advertising. Thus, the FTC argued that the advertising implied that the safety and efficacy claims were for the product as a whole rather than the ingredients or components as stated in the advertising, despite that the advertising actually focused on the ingredients and components of the dietary supplement products, rather than the products themselves.

Petitioners had purposefully used scientific studies of the active ingredients and components of the products to develop the products at issue and then designed the advertisements to conform to the results of the studies. The referenced studies consisted of independent, double-blind, placebo-controlled clinical trials and scientific studies found in well-respected medical journals. Petitioners relied upon these studies and comments for scientific

support that the ingredients in the products were safe and effective as represented. Among the studies were numerous clinical studies and comments expressed by independent "think-tank" organizations and others, as well as meta-studies such as the CANTOX Report and the RAND Report. *See* note 7, *infra.* These reports concluded that the major ingredients of the products at issue – ephedra/ephedrine and caffeine – were safe and effective in promoting weight loss as represented.

Upon cross-motions for summary judgment, the district court denied Petitioners' motions and granted summary judgment in favor of the FTC. (App. 86a.) In so doing, the court rejected Petitioners' arguments that the advertising had protection under the First Amendment (App. 20a-22a) and that the FTC's "competent and reliable scientific evidence" standard was void for vagueness (App. 22a-25a).

On appeal, Petitioners challenged the district court's rejection of their two First Amendment arguments. Moreover, Petitioners argued that the district court resolved as a matter of law issues that are properly reserved for a trier of fact. In their petition for rehearing, Petitioners also argued that the court's opinion eviscerated the statutory scheme Congress promulgated with DSHEA. Despite the district court's constitutional errors and the circuit splits the case created, the Eleventh Circuit Court of

Appeals summarily disposed of all of Petitioners' arguments in a three-sentence *per curiam* opinion.[4]

REASONS FOR GRANTING THE PETITION

I. The Eleventh Circuit's Decision Conflicts with Decisions of the D.C. Circuit in Two Important Areas of First Amendment Jurisprudence.

The court of appeals' decision has effectively and unnecessarily chilled the First Amendment rights of dietary supplement manufacturers, including Petitioners, to advertise their products. Furthermore, the court's ruling is now in conflict with the D.C. Circuit in regard to the constitutional right to commercial speech for such dietary supplement manufacturers. *See Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

The advertising in question involved commercial speech protected by the First Amendment. *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980). As explained above, in an effort to comply with the FTC's standards, Petitioners based their advertising claims upon ingredient-specific substantiation, namely, independent, double-blind, placebo-controlled clinical trials of the components and ingredients of the referenced products. The FTC conceded in discovery that "it did not contend that any individual statement in the advertisement was

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[4] Because the court of appeals merely stated that it agreed with the district court's "well-reasoned" opinion, this petition treats the district court's opinion as that of the court of appeals.

not 100% accurate." Nevertheless, the court failed to analyze Petitioners' advertising under the standards of *Central Hudson*. Moreover, the court failed to require the FTC to provide any clarity to its vague standard of "competent and reliable scientific evidence."

A. Commercial Speech.

Under *Central Hudson*, to determine the constitutionality of commercial speech, the courts apply a four-step process:

> At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than necessary to serve that interest.

Central Hudson, 447 U.S. at 566.

The first prong of the *Central Hudson* test (speech must not be false) applies only to *inherently false* advertising. As this Court has explained:

> Truthful advertising related to lawful activities is entitled to the protections of the First Amendment. But when the particular content or method of the advertising suggests that it is inherently misleading or when experience has proved that in fact such advertising is subject to abuse, the States may impose appropriate restrictions. Inherently misleading advertising may be prohibited entirely. But the States may not place an absolute prohibition on . . . potentially misleading information . . . if the information also may be presented in a way that is not deceptive.

In re R.M.J., 455 U.S. 191, 203 (1982); *see, e.g., Alexander v. Cahill*, 598 F.3d 79, 89 (2d Cir. 2010); *Borgner v. Brooks*, 284 F.3d 1204, 1210-11 (11th Cir. 2002).

In the proceedings below, the FTC claimed, and the court agreed, that Petitioners' advertising was inherently false. (App. 58a-59a.) As explained by the court, the advertising claims at issue necessarily were "inherently false" because clinical testing had not been conducted upon the products themselves. (App. 58a & n.21.) But other courts

have rejected this sort of "blanket falsity" in the context of regulations by the FDA. *See Pearson*, 164 F.3d at 655.

In *Pearson*, a group of dietary supplement manufacturers filed suit against the FDA in connection with the FDA's rejection of certain health claims made by the manufacturers. *Pearson v. Shalala*, 14 F. Supp. 2d 10, 14 (D.D.C. 1998). The FDA, applying the "significant scientific agreement" standard set forth in 21 C.F.R. § 101.14, determined that the supporting evidence for the claims as offered by the manufacturers was insufficient to meet the standard but never explained how it measured evidence under the standard. *Pearson*, 164 F.3d at 653. Thus, the FDA declined to authorize the manufacturers' claims, finding the claims to be "*inherently* misleading and thus entirely outside the protection of the *First Amendment* as commercial speech." *Pearson*, 164 F.3d at 655 (emphasis in original). In addition, the FDA declined to consider an alternative to allow the manufacturers to make the claims with "corrective disclaimers" if the claims were only "potentially misleading." *Id.* at 654-55, 657. After the district court affirmed the FDA's decision, the court of appeals reversed. *Id.* at 651.

The D.C. Circuit first rejected the FDA's blanket denial of the health claims as "inherently misleading."

> As best we understand the government, its first argument runs

> along the following lines: that health claims lacking "significant scientific agreement" are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment *at the point of sale*. It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous . . . . We reject it.

Id. at 655 (internal citations omitted; emphasis in original).

The D.C. Circuit then addressed the FDA's argument that the health claims could be at least "potentially misleading." *Id.* Applying *Central Hudson*, the court held that there was not a "reasonable fit between the government's goals" of protecting public health and preventing consumer fraud and "the means chosen to advance those goals," namely, the rejection of plaintiffs' proposed health claims without consideration of disclaimers. *Pearson*, 164 F.3d at 656-58. In particular, the D.C. Circuit held that under the First Amendment commercial speech doctrine, there is a "preference for disclosure over outright suppression" and for "less restrictive and more precise means" of regulating commercial speech. *Id.* at 657-58. In the opinion of the court, the FDA's rejections of disclaimers without a showing that they were

insufficient to meet the government's goals demonstrated a disregard for "less restrictive" means of regulating the speech under the First Amendment. *Id.* at 659. As explained by the court, "[i]t is clear, then, that when government chooses a policy of suppression over disclosure – at least where there is no showing that disclosure would not suffice to cure misleadingness – government disregards a 'far less restrictive' means." *Id.* at 658.

The decision in this case directly conflicts with the D.C. Circuit's holdings regarding commercial speech and dietary supplements. The advertising at issue is not inherently false. The FTC conceded that the statements were literally true. *See Alliance for Natural Health US v. Sebelius,* – F. Supp. 2d –, 2010 WL 2110071, *11 (D.D.C. May 27, 2010) (finding the FDA's position that certain health claims were misleading was "particularly troubling" when the FDA had admitted that the claims were "literally true"). Even without the FTC's concession, the claims could not be considered "inherently false" when the resolution of whether the claims were false or unsubstantiated depended upon hundreds of pages of material, testimony, and experts who evaluated and opined as to the advertising claims and their substantiation.

Like the FDA, with its lack of analysis of the health claims in *Pearson* and *Alliance for Natural Health*, the FTC here has merely made an unsupported determination that Petitioners' advertising must necessarily be inherently false. In contrast to the court in *Pearson,* however, the courts

below accepted the FTC's unsupported determination. Manufacturers of dietary supplements are now subject to very differing standards, and their liability depends only upon the district in which suit is brought. Because the remedies a court may impose are potentially quite substantial (in this case, the court ordered consumer redress of almost $16 million), manufacturers will almost certainly adhere to the more speech-restrictive standard. This Court should address the conflict.

B. Vagueness.

The Eleventh Circuit's rejection of Petitioners' vagueness challenge to the FTC's "competent and reliable scientific evidence" standard also conflicts with the decision in *Pearson*. In *Pearson*, the plaintiffs argued that the FDA had an obligation to "articulate a standard a good deal more concrete than the undefined 'significant scientific agreement.'" *Pearson*, 164 F.3d at 654. In response, the FDA claimed that the "significant scientific agreement" standard was based upon "objective factors" and that its procedures for approving health claims under such standards satisfied constitutional muster. *Id.* at 653. The court of appeals disagreed, finding that the FDA was required to "giv[e] some definitional content to the phrase 'significant scientific agreement.'" *Id.* at 660.[5] As explained by

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[5] The court in *Pearson* analyzed the plaintiffs' claim pursuant to the APA's arbitrary and capricious standard. *Id.* at 660. As that court recognized, however, a First Amendment analysis would have reached the same conclusion. *Id.* at 660 & n.12.

the court, "[t]o refuse to define the criteria it is applying is equivalent to simply saying no without explanation." *Id.*

Here, the FTC's refusal (and the court's approval of such refusal) to define or provide explicit direction as to what qualifies as "competent and reliable scientific evidence" has created uncertainty and guesswork for the dietary supplement industry. At present, there are only a few relevant publications of the FTC that purport to offer "guidance" to the dietary supplement industry when developing advertising. Moreover, the referenced "guidance" does not provide sufficient certainty about the criteria the FTC uses to evaluate the scientific support of ingredient-specific claims. The FTC has not established any requirements for size, duration, or protocol for any scientific study, or any single fixed formula for the number or type of studies needed to substantiate a claim. The FTC only argues that its standard of "competent and reliable scientific evidence" is based upon "flexibility" in the type and amount of evidence required depending on the nature of the claim and how it is presented and qualified. *See FTC publication, Dietary Supplements: An Advertising Guide for the Industry.* This purported "guidance" provides little when faced with punitive enforcement proceedings such as the case at bar. Under these circumstances, the dietary supplement industry, including Petitioners, cannot be expected to review the FTC's vague standard and have any confidence as to whether the FTC would consider their substantiation for their advertising claims adequate

or not. The Court should resolve this conflict as well.

II. The Eleventh Circuit's Decision Conflicts with an Existing Statutory Scheme.

The opinion below not only creates a circuit split; it also eviscerates the existing statutory scheme that Congress created with the enactment of DSHEA. As noted earlier, DSHEA treats dietary supplements as a subset of food, not as drugs, and hence, it exempts them from the pre-market testing required of drugs. Instead, manufacturers of dietary supplements may rely on the testing of their active ingredients to manufacture and advertise their products. Under the new standard created by the opinions below, the FTC can trump the provisions of DSHEA as enforced by the FDA and mandate pre-market testing of the entire product, even though Congress specifically exempted dietary supplement manufacturers from that requirement.

Under DSHEA, dietary supplements are excluded from any requirement for pre-market clinical testing and scientific review. *See* 21 U.S.C. § 342(f)(1)(a). Furthermore, manufacturers of these supplements are permitted to make certain claims regarding the benefits of their products without prior FDA approval so long as the claim is based upon "substantiation" that is "truthful and not misleading." 21 U.S.C. § 343(r)(6). Given these statutory requirements, Petitioners developed and focused their products and the related advertising

upon the components and ingredients of the products, rather than the products as a whole.

As substantiation, Petitioners relied upon ample evidence of independent, double-blind, placebo-controlled clinical trials of the components and ingredients, a meta-analysis of those clinical trials, or both. Petitioners used this ingredient-specific substantiation as the basis for the advertising of their dietary supplement products by placing the same statistical figures and information found in the referenced studies explicitly in the advertisements. In other words, wherever Petitioners made a claim regarding any health benefits, Petitioners had a specific clinical study or scientific paper that supported the claim. For example, an advertisement for Thermalean stated that the "thermogenic components" of Thermalean resulted in 300% decrease in stored fat versus use of a placebo and 600% increase in total weight loss versus use of a placebo. These figures came from specific conclusions reached by respected scientists and clinical researchers in clinical studies involving ephedrine and caffeine.[6]

On its face, the evidence proffered by Petitioners meets the standards of the FDA under DSHEA with respect to health claims for dietary supplements. Under the FDA standard of

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[6] The studies relied upon by Petitioners were consistent with the FTC's expert's opinion that claims required substantiation in the form of appropriately analyzed, independent, well-designed, well-conducted, randomized, double-blind, placebo-controlled clinical trials.

"significant scientific agreement," a health claim is authorized for a dietary supplement when the FDA determines:

> based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is support by such evidence.

21 C.F.R. § 101.14(c).

As demonstrated by the amounts of scientific analysis and clinical trials, Petitioners had such substantiation to support the truthfulness of their claims on their products in accordance with DSHEA. *See* 21 U.S.C. § 343(r)(6). In addition, Petitioners had the referenced studies, as well as the advertising claims at issue, reviewed by and supported by a medical doctor and a pharmacologist prior to publication. *See, e.g., FTC v. Lane Labs-USA, Inc.*, 2009 WL 2496532, *8 (D.N.J. Aug. 11, 2009) (noting that prior to distribution of the advertisements in question, the defendant consulted experts who opined the scientific evidence supported the claims made in advertising). In short, it is readily apparent that Petitioners complied with the governmental

requirements for dietary supplements under DSHEA.[7]

Ingredient-specific substantiation such as this has been used by other dietary supplement manufacturers, as well as other industries that are not required to conduct pre-market testing and clinical studies. For example, toothpaste producers often refer to the active ingredient (sodium flourophosphate) in their product in providing substantiation for their advertising claims even though a clinical study of the product itself may not have been done. With respect to dietary supplements, advertising based upon ingredient-specific substantiation is particularly effective in light of the level of sophistication associated with the typical dietary supplement consumer.[8]

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[7] The meta-analysis used for substantiation included the following: (1) CANTOX Health Services International, *Safety Assessment and Determination of a Tolerable Upper Limit for Ephedra*, December 19, 2000 (the "CANTOX Report); and (2) Shekelle P., Morton, S., Maglione, m., et al., *Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects*, Evidence Report/Technology Assessment No. 76 (Prepared by Southern California Evidence-based Practice Center, RAND, under Contract No. 290-97-0001, Task Order No. 9), AHQR Publication No. 03-E022, Rockville, MD: Agency for Healthcare Research and Quality. February, 2003 (the "RAND Report"). Both of these analyses examined most of the same studies upon which Petitioners relied to support their advertising claims.

[8] The record below included the survey conducted by Dr. Glen Richey that revealed that the consumer intent to purchase the products at issue was driven by the claims in the advertisements regarding the components and ingredients, not the product. The survey indicated that purchasers of dietary

Contrary to the standards laid out by Congress and the FDA, the courts below held that that ingredient-specific scientific data could not substantiate the advertising claims. In other words, ingredient-specific substantiation for dietary supplements could not constitute "competent and reliable scientific evidence" under the FTC's standards. Under this ruling, to satisfy the FTC's standard of "competent and reliable scientific evidence," dietary supplement manufacturers are now subject to a *de facto* requirement to conduct pre-market clinical studies of the product itself. Such a precedent effectively eliminates DSHEA's exclusion of dietary supplements from the pre-market testing and clinical analysis typically reserved for drugs under the FFDCA. Moreover, it undermines the purpose of the enactment of DSHEA and the intent of Congress to provide greater access to dietary supplements and information with less regulation.[9] This Court's intervention is necessary to address the conflict between the statue and the holding below.

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supplements are more educated consumers than the ordinary consumer and can differentiate between whether a claim is about an ingredient or the product as a whole.

[9] It is important to recognize that, without the court's intervention, the FTC could not have issued a rule requiring pre-market clinical testing for dietary supplements without obtaining prior congressional approval and conducting rulemaking proceedings. *See* 15 U.S.C. § 57a.

III. The Eleventh Circuit's Decision Conflicts with the Decisions of Other Courts of Appeals in False Advertising Cases.

In affirming the district court's grant of summary judgment, the court of appeals created a circuit split on not one, but two, important issues in false advertising cases. First, the court determined that the advertisements were misleading as a matter of law. *Compare, e.g., FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 39-41 (D.C. Cir. 1985) (whether advertising is deceptive is a question of fact); *Nat'l Bakers Servs., Inc. v. FTC*, 329 F.2d 365, 367 (7th Cir. 1964) (same). Second, the court held that Petitioners' substantiation of its claims was inadequate as a matter of law. *Compare FTC v. Pantron I Corp.*, 33 F.3d 1088, 1096 (9th Cir. 1994) (whether a claim is substantiated is a question of fact).

The record in this case contained an abundance of evidence that created material factual disputes sufficient to withstand summary judgment. Petitioners submitted substantial amounts of evidence in the form of documents and testimony related to the meaning of the advertising claims at issue and the scientific support for such claims. In contrast, the FTC presented virtually nothing other than the testimony of its own experts who admittedly were never presented with copies of the actual advertisements at issue.

With respect to the advertising claims, Petitioners presented evidence that the components

and ingredients of the products at issue were the focus of Petitioners' advertising claims, rather than the products as a whole. Although "[t]he meaning of an advertisement, the claims or net impressions communicated to reasonable consumers, is fundamentally a question of fact," *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 957-58 (N.D. Ill. 2006), *citing Nat'l Bakers,* 329 F.2d at 367, the court below determined that the question of fact "may be resolved by the terms of the advertisement itself or by evidence of what consumers interpreted the advertisement to convey." (App. 29a.)

In considering charges of false and deceptive advertising, the consumer's "impression is the only true measure of deceptiveness" and thus, "if the lower court confronts an advertisement involving 'literally true or grammatically correct' statements, the trial judge cannot make a finding of deceptiveness unless the parties provide 'evidence of substance' about what 'the person to whom the advertisement is addressed find[s] to be the message.'" *Brown & Williamson Tobacco Corp.*, 778 F.2d at 39-41 (citations omitted). On this point, Petitioners submitted expert consumer survey evidence into the record that demonstrated that consumers interpreted the advertising at issue to focus on the components and ingredients, rather than the products. The FTC presented only the advertisements themselves. As Petitioners noted in their response to the FTC's motion for summary judgment, the FTC's reliance on the advertisements alone contradicted its own expert's opinion that only

the recipient of the advertising could ascertain the content and meaning thereof.

Instead of construing the evidence in the light most favorable to Petitioners, *see Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986), the court focused solely on whether the FTC's alleged claims were implied from the face of the advertisements. The court found that the advertisements made numerous *implicit* claims regarding the safety and efficacy of the products themselves and disregarded the literal language of the advertisements, which *explicitly* focused on the components and ingredients contained within the product. A rational trier of fact could have concluded that the express advertising claims were focused on the ingredients, rather than the products. The district court, however, dismissed this distinction as "meaningless." (App. 43a.)

The clinical studies and scientific support that Petitioners submitted as substantiation for the advertising claims similarly focused on the components and ingredients of the dietary supplement products. Petitioners presented the court with substantial evidence of independent, double-blind, placebo-controlled clinical trials of the components and ingredients, a meta-analysis of those clinical trials, or both. The clinical trials and other scientific evidence that Petitioners submitted created a question of fact as to whether Petitioners possessed "competent and reliable scientific evidence" to substantiate the advertising claims. From the evidence presented below, a reasonable trier of fact could have concluded that the

components and ingredients in the products at issue were safe and effective as advertised. The court nonetheless held as a matter of law that Petitioners' substantiation was inadequate.

Whether a manufacturer of dietary supplements has an opportunity to present its evidence to a trier of fact now depends on the circuit in which the FTC brings suit. This uncertainty, like the uncertainty regarding a manufacturer's commercial speech rights, neither promotes greater consumer information nor reduces government regulation. *See Nutritional Health Alliance*, 144 F.3d at 224. This Court should resolve that uncertainty.

CONCLUSION

Based upon the foregoing, Petitioners respectfully request that the Court grant their petition for writ of certiorari.

Respectfully submitted,

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IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 09-10617

Federal Trade Commission,
Plaintiff-Counter-Defendant-
Appellee,

v.

National Urological Group, Inc.,
d.b.a. Warner Laboratories,
Defendant-Counter-Claimant-
Appellant,
National Institute for Clinical
Weight Loss, Inc.
Defendant-Counter-Claimant,
Hi-Tech Pharmaceuticals, Inc.,
Corporations, Jared Wheat, Thomasz
Holda, individually and as officers of
the corporations, Stephen Smith,
individually and as officer of National
Urological Group, Inc., and National
Institute for Clinical Weight Loss,
Inc., Terrill Mark Wright, M.D.,
individually,
Defendants-Appellants.

Appeal from the United States District Court
for the Northern District of Georgia

Filed U.S. Court of Appeals, Eleventh Circuit
December 15, 2009, John Ley, Clerk

Before DUBINA, Chief Judge, BIRCH, and BLACK, Circuit Judges.

PER CURIAM

After having thoroughly reviewed the record, the briefs and having heard oral argument in this case, we are of the opinion that the well-reasoned decision and the judgment of the district court should be and is **AFFIRMED.**

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

Federal Trade Commission,	:	
Plaintiff,	:	Civil Action No.
	:	No. 1:04-CV-3294-CAP
v.	:	
	:	
National Urological Group, Inc., d/b/a Warner Laboratories, et al.,	:	
Defendants.	:	

ORDER

This matter is before the court on the following motions: (1) the defendants' motion for summary judgment [Doc. No. 168]; (2) defendant Hi-Tech Pharmaceuticals, Inc.'s ("Hi-Tech") motion for summary judgment [Doc. No. 170]; (3) the plaintiff's motion for summary judgment [Doc. No. 172]; and (4) the defendants' motion to strike the declaration of Jennifer A. Thomas [Doc. No. 214].

I. *Case Overview*

A. *The Plaintiff*

The Federal Trade Commission ("FTC") is an independent agency of the United States Government created by statute. 15 U.S.C. §§ 41-58. The FTC is tasked with enforcement of the Federal Trade Commission Act (the "FTC Act"). The FTC Act prohibits unfair or deceptive acts or practices in or affecting commerce. 15 U.S.C. § 45(a). The FTC Act also

prohibits false advertisements for food, drugs, devices, services, or cosmetics in or affecting commerce. 15 U.S.C. § 52.

To aid its enforcement of the FTC Act, the FTC has promulgated regulations that require advertisements: (1) to be truthful and not misleading, and (2) to be supported by adequate substantiation for product claims prior to dissemination. The FTC refers to a violation of the former as a "falsity claim," while a violation of the latter requirement is a "lack of reasonable basis ("LORB") claim."

B. *The Defendants*

Defendants National Urological Group ("NUG"), National Institute for Clinical Weight Loss ("NICWL")[1] and Hi-Tech (collectively, the "corporate defendants") are corporations that are or were marketing, distributing and selling weight loss and/or erectile performance dietary supplements under the brand names Thermalean, Lipodrene, and/or Spontane-ES. Defendants Jared Wheat and Thomasz Holda are or were officers and shareholders of NUG and Hi-Tech, and were officers and shareholders of NICWL prior to its dissolution. Defendant Stephen Smith is or was an officer and shareholder of NUG, and was an officer and shareholder of NICWL before its dissolution. Defendant Terrill Mark Wright, M.D., is a medical doctor who promoted the dietary supplements at issue in this case.

C. *Brief Synopsis of Facts*

According to the defendants, the FTC began investigating their advertising practices in May of 2002. During the course of the investigation, the FTC

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[1] NICWL dissolved in 2004.

requested from the defendants the substantiation for their advertising. The defendants allegedly complied and provided the FTC with substantiation based on each individual active ingredient in their dietary supplements ("ingredient-specific substantiation"), as opposed to substantiation based on the product as a whole.

While the FTC investigation was ongoing, the United States Food and Drug Administration[2] ("FDA") filed a complaint for injunctive relief against the corporate defendants and Wheat in his individual capacity (collectively, the "FDA defendants"), alleging that they introduced misbranded drugs into commerce. Not long after the suit was filed, the FDA defendants entered into a consent decree with the FDA (the "Consent Decree"). The Consent Decree regulates the FDA defendants' behavior along three pertinent veins. First, before the FDA defendants can sell a dietary supplement that is not considered a drug, the Consent Decree requires them to retain an independent expert to inspect their product labeling, including their promotional materials and internet web sites, and certify to the FDA that the FDA defendants are not making drug claims for their products. In addition to the independent expert's report, the FDA defendants must submit to the FDA a written report that details, among other things, the actions

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[2] The FTC and the FDA work together under an agreement governing the division of responsibilities between the two agencies. As applied to dietary supplements, the FDA has primary responsibility for claims on product labeling, including packaging, inserts, and other promotional material distributed at the point of sale. The FTC has primary responsibility for claims in advertising, including print and broadcast ads, infomercials, catalogs, and similar direct marketing materials.

they have taken to comply with the FDA Consent Decree. After this, the FDA defendants must await the FDA's approval to resume or initiate operations. After resuming sales, the FDA defendants are prohibited from "directly or indirectly introduc[ing] or deliver[ing] for introduction into interstate commerce, or directly or indirectly caus[ing] the introduction or delivery for introduction into interstate commerce of, any misbranded or unapproved new drug." Consent Decree, ¶ 4(A) [Doc. No. 168, Ex. I]. Finally, the Consent Decree permits FDA representatives to make unannounced inspections of the FDA defendants' facilities, during which the FDA is allowed to investigate, among other things, all equipment, finished and unfinished drugs and dietary supplements, and all labeling, including promotional materials and internet site information. If the FDA determines that the FDA defendants are not in compliance with the Consent Decree, the FDA may take any other reasonable measures to monitor and ensure the FDA defendants' continuing compliance.

On November 10, 2004, months after the defendants entered into the Consent Decree, the FTC filed the instant suit pursuant to Section 13(b) of the Act, 15 U.S.C. § 53(b),[3] to secure injunctive and other equitable relief against the defendants. In its complaint, the FTC asserts that the defendants have violated Section 5 of the Act, 15 U.S.C. § 45(a),[4] and

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[3] Section 13(b) enables the FTC to seek equitable relief from the district court.

[4] Section 5 prohibits unfair or deceptive acts or practices.

Section 12 of the Act, 15 U.S.C. § 52.[5] Specifically, the FTC claims that the defendants have made deceptive representations to the public in their advertisements for the dietary supplements Thermalean, Lipodrene, and Spontane-ES. The FTC has petitioned this court for injunctive relief as well as relief in the form of consumer redress and disgorgement of profits.

On August 24, 2007, the defendants, defendant Hi-Tech, individually, and the FTC filed cross motions for summary judgment [Doc. Nos. 168, 170, and 172]. On December 13, 2007, the defendants filed a motion to strike the affidavit of Jennifer Thomas [Doc. No. 214].

II. *The Defendants' Motion to Strike the Affidavit of Jennifer Thomas [Doc. No. 214]*

Before considering the parties' motions for summary judgment, the court will address the defendants' motion to strike the declaration of Jennifer A. Thomas [Doc. No. 214]. Thomas is Director of the Division of Enforcement in the Center for Food Safety and Applied Nutrition at the FDA. The FTC filed Thomas's declaration in response to the defendants' motion for summary judgment and Hi-Tech's motion for summary judgment on November 5, 2007. Prior to filing Thomas's declaration, the FTC did not disclose Thomas to the defendants as a party likely to have discoverable information. The defendants contend that the FTC's failure to identify Thomas at an earlier date was prejudicial to their case and a violation of the Federal Rules of Civil Procedure. Accordingly, the defendants request that the court strike her affidavit.

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[5] Section 12 prohibits false advertisements for food, drugs, devices, services, or cosmetics affecting commerce.

A. *The Defendants' Motion to Strike Is Denied*

The courts in this district have repeatedly found that it is improper to strike an affidavit attached to a summary judgment brief. Lentz v. Hospitality Staffing Solutions, LLC, No. 1:06-cv-1893-WSD, 2008 U.S. Dist. LEXIS 6291, at *30-31 (N.D. Ga. Jan. 28, 2008) (noting that Federal Rule of Civil Procedure 12(f) permits the court to strike a pleading, not an affidavit attached to a motion for summary judgment). As this court stated in Lentz, "the proper method to challenge such an affidavit is to challenge the admissibility of the evidence contained in the affidavit." Id.; see also Pinkerton & Laws Co. v. Roadway Express, Inc., 650 F. Supp. 1138, 1141 (N.D. Ga. 1986) (concluding that a party should file a notice of objection rather than a motion to strike to challenge the admissibility of evidence in an affidavit).

Because a motion to strike is a procedurally improper vehicle for challenging Thomas's affidavit, the court must deny the defendants' motion. However, the court "may only consider admissible evidence when deciding a motion for summary judgment," and the defendants' motion raises important questions regarding the admissibility of the Thomas affidavit. Id. Accordingly, the court, 'in the interest of efficiency," will "proceed to assess the admissibility of the challenged affidavit." Spratlin Outdoor Media, Inc. v. City of Douglasville, No. 1:04-cv-3444-JEC, 2006 U.S. Dist. LEXIS 20797, at *13 (N.D. Ga. Mar. 27, 2006).

B. *The Thomas Declaration is Inadmissible*

Federal Rule of Civil Procedure 26(a)(1) requires parties to provide initial disclosures including "the name and, if known, the address and telephone number of each individual likely to have discoverable information .

. . that the disclosing party may use to support its claims or defenses, unless the use would be solely for impeachment." By rule, the obligation to disclose pertinent parties is continuing, so that a party must supplement its disclosures or discovery responses "in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing." Fed. R. Civ. P. 26(e)(1)(A). If a party does not "provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1).

It is undisputed that the FTC neither initially disclosed Thomas as a potential witness nor listed her as a witness in response to pertinent interrogatories. Although the FTC supplemented its initial disclosures in February 2006 to note that an "as yet unknown" FDA representative may have information relevant to the case, the FTC did not further supplement its disclosures in April 2006 when it identified Thomas as the FDA representative that it intended to use as a witness. FTC's First Am. Initial Disclosures, ¶ 3(N) [Doc. No. 118]. In fact, the FTC did not notify the defendants of Thomas or indicate in any other way that it had identified a FDA witness until it filed her declaration at the end of 2007.

The FTC does not offer justification for its substantial delay in disclosing Thomas as a witness, but instead simply contends that her declaration should be

admitted because the defendants were neither surprised nor prejudiced by its failure to disclose her as a witness at an earlier date. Essentially, the FTC contends that its disclosure in February 2006 that it was looking for a witness was enough to put the defendants on notice of Thomas's potential role in this case. Moreover, the FTC contends that it was not required to disclose Thomas because she was a "witness used solely for impeachment," and thus was not subject to Federal Rule of Civil Procedure 26. Fed. R. Civ. P. 26(a)(1).

The FTC's arguments are unconvincing. First, the fact that the FTC notified the defendants that they were looking for a witness in 2006, without more, does not mean that the defendants were not surprised when such a witness suddenly appeared on the record a year and a half later. Moreover, the court is convinced that the FTC's failure to disclose Thomas's identity was prejudicial to the defendants. Thomas's declaration addresses the meaning and effect of the Consent Decree, a topic of critical importance to the defendants' summary judgment briefs. The FTC's failure to disclose Thomas as a potential witness prevented the defendants from deposing her or anticipating her testimony before expending the significant resources required to file their dispositive motions. Such a failure can hardly be considered harmless.

Similarly, this court cannot conclude that the FTC presented Thomas's declaration "solely for impeachment." Impeachment evidence is evidence that is "offered to discredit a witness . . . to reduce the effectiveness of her testimony by bringing forth evidence which explains why the jury should not put faith in her or her testimony." Chiasson v. Zapata Gulf Marine Corp., 988 F.2d 513, 517 (5th Cir. 1993).

Although Rule 26(a)(1) does not require a party to disclose a witness that it intends to use "solely for impeachment," the Eleventh Circuit has indicated that this is a narrow exception that should be limited to circumstances where the evidence offered by the witness plays no role other than impeachment. See Coolev v. Great Southern Wood Preserving. 138 Fed. Appx. 149, 161 (11th Cir. 2005) (affirming a district court's decision to exclude affidavits because the plaintiff failed to show that the evidence was offered solely for impeachment).

Here, Thomas's declaration does not simply discredit one particular witness or even a group of witnesses; rather, it is substantive evidence supporting the FTC's defense to one of the defendants' key summary judgment contentions. In their motion for summary judgment, the defendants have argued that the FTC's action is not in the public interest because all of the relief the FTC seeks has already been achieved by the FDA's Consent Decree. Thomas's declaration, which the FTC offered "to clarify many of the facts surrounding the FDA consent decree," provides substantive evidence that the relief the FTC seeks is not redundant and that the action the FTC pursues is in the public interest. FTC's Resp. to Defs.' Mot. for Summ. J., p. 52 [Doc. No. 195]. This evidence was provided to preserve the FTC's case by demonstrating that there is a genuine issue for trial. Accordingly, it cannot simply be considered impeachment evidence offered solely "to discredit" the defendants.

The FTC's reliance on Sessoms v. Ghertner & Co., C.A. No. 3:05-0257, 2006 U.S. Dist. LEXIS 29863 (M.D. Tenn. April 25, 2006), is misplaced. In Sessoms, the defendant, in response to a summary judgment motion,

sought to impeach specific deposition testimony by filing declarations of individuals not previously disclosed in interrogatories or initial disclosures. Id. at *9. That is not the situation here, where Thomas's declaration is offered to rebut legal arguments and interpret the Consent Decree rather than to simply impeach deposition testimony.

The court concludes that Thomas's declaration was not offered solely for impeachment, and thus holds that the FTC was not exempt from disclosing her as required by Federal Rule of Civil Procedure 26. The FTC has offered no justification for its year and a half delay in disclosing Thomas to the defendants, and the court concludes that this delay was harmful and inexcusable. Consequently, the court will not consider Thomas's declaration or its supporting exhibits in any summary judgment proceeding currently before the court.

III. ***Summary Judgment Motions***

On August 24, 2007, defendant Hi-Tech individually filed a motion for summary judgment [Doc. No. 170],[6] the defendants collectively filed a motion for summary judgment [Doc. No. 168] and the FTC filed a motion for summary judgment [Doc. No. 172]. These summary judgment motions will be addressed in turn.

A. ***Summary Judgment Standard***

Summary judgment is proper where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,

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[6] Hi-Tech also joined in the defendants' collective motion for summary judgment, but filed an individual motion to address a liability defense not shared by its co-defendants.

show that there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the initial burden of showing that there is no genuine issue of material fact. See Celotex Corp. v. Catrett. 477 U.S. 317, 323 (1986). This may be accomplished by showing that the nonmoving party will be unable to "establish the existence of an element essential to [the nonmoving] party's case, and on which [the nonmoving] party will bear the burden of proof at trial." Id. at 322.

Once the moving party has met its burden, the burden shifts to the nonmoving party to "designate specific facts showing that there is a genuine issue for trial." Id. at 324 (internal quotation marks omitted). There is a genuine issue if the combined body of evidence, viewed in the light most favorable to the nonmoving party, would allow a reasonable jury to find in favor of the nonmoving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). In other words, the relevant inquiry is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." Id. at 251-52. When, as here, a district court is presented cross motions for summary judgment on the same issues, "[t]he court must rule on each party's motion on an individual and separate basis, determining, for each side, whether a judgment may be entered in accordance with the Rule 56 standard." 10A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 2720, at 335-36 (3d ed. 1998) (footnote omitted).

B. ***Hi-Tech's Motion for Summary Judgment [Doc. No. 170]***

Hi-Tech premises its motion for summary judgment on one simple contention: it claims that it did not manufacture, advertise, or market the Lipodrene product at issue in this case and, thus, is not liable on the FTC's allegations. Although Hi-Tech admits that it has produced and marketed multiple products under the name Lipodrene, it claims that these products are "completely different in look and formulation" from the Lipodrene that its co-defendant, NUG, marketed in the advertisements targeted in this action. Hi-Tech's Resp. to FTC's Statement of Additional Facts, ¶ 9 [Doc. No. 202, Ex. 1]. Hi-Tech contends that it did not participate in or fund the advertisements for the old Lipodrene or any other product, and thus, cannot be held liable for them.

The FTC argues that Hi-Tech is not entitled to summary judgment because Hi-Tech participated in all of the advertising at issue in this case, particularly the Lipodrene advertisements. Specifically, the FTC contends that Hi-Tech, NUG, and NICWL acted as a common enterprise. Accordingly, the FTC contends that Hi-Tech should be jointly and severally liable with its corporate co-defendants for all of the advertising at issue in this case.

1. ***Legal Standard for Finding a Common Enterprise***

"The general rule is that, absent highly unusual circumstances, the corporate entity will not be disregarded." Collier & Son Corp. v. FTC, 427 F.2d 261, 266 (6th Cir. 1970). However, "where the public interest is involved, as it is in the enforcement of Section 5 of the Federal Trade Commission Act, a strict adherence to common law principles is not

required . . . where strict adherence would enable the corporate device to be used to circumvent the policy of the statute." Id. at 267 (making this statement in the context of determining whether a parent should be held liable for the acts of its subsidiary). Thus, in situations where corporations are so entwined that a judgment absolving one of them of liability would provide the other defendants with "a clear mechanism for avoiding the terms of the order," courts have been willing to find the existence of a common enterprise. See Delaware Watch Co. v. FTC, 332 F.2d 745, 746-47 (2d Cir. 1964) (affirming a FTC order holding a company liable because it was part of a "maze of interrelated companies" through which "the same individuals were transacting an integrated business"). When corporations act as a common enterprise, each may be held liable for the deceptive acts and practices of the other. CFTC v. Wall Street Underground, Inc., 281 F. Supp. 2d 1260, 1271 (D. Kan. 2003) (citing Sunshine Art Studios, Inc. v. FTC, 481 F.2d 1171, 1175 (1st Cir. 1973)).

When determining whether a common enterprise exists, "the pattern and frame-work of the whole enterprise must be taken into consideration." Delaware Watch Co., 332 F.2d at 746 (citations omitted). Some of the factors that courts evaluate to determine whether a common enterprise exists include common control; the sharing of office space and officers; whether business is transacted through a maze of interrelated companies; the commingling of corporate funds and failure to maintain separation of companies; unified advertising; and evidence that reveals that no real distinction exists between the corporate defendants. FTC v. Wolf, No. 94-8119-CIV-

FERGUSON, 1996 U.S. Dist. LEXIS 1760, at *22-23 (S.D. Fla. Jan. 30, 1996) (citations omitted).

2. ***Application of Legal Standard to Facts***

In this case, it is clear that all three companies at issue operated as a common enterprise. First, all three companies were under the common control of Wheat and Holda, and were at least influenced by Smith. Wheat served as the president and primary decision maker of all three companies. He developed all of the products at issue in this case, owned all of their trademarks, developed all of their advertising (or at least provided the information for all of the advertisements), wrote checks for all three companies, made deposits and withdrawals on behalf of all three companies, and had the authority to enter into contracts and terminate contracts for all three companies.

Holda likewise served as an officer of all three companies. In that role, he participated in business decisions. Holda also ran the shipping operations for each of the companies and testified that he reviewed the advertisements for errors before they were disseminated.

Smith served as an officer of NICWL and NUG, and served as an independent contractor for Hi-Tech beginning in 2003. In all three companies, Smith served as the employee/independent contractor manager. Smith, like Holda, testified that he reviewed all of the advertisements for errors.

Wheat, Holda, and Smith ran the three companies out of the same office space in an integrated fashion. For instance, Hi-Tech – the only company with its name on the door – assumed the duty of leasing the office space, often served as the addressee and mail distributor for the other companies, and

ordered goods on behalf of the other companies so that all of the companies could save money.[7] Similarly, NICWL served as the payroll manager for itself, NUG, and other affiliated, non-party companies. All three companies shared in the allocation of a number of indirect costs and expense items, including bank charges, credit card fees, depreciation, and - most importantly - consulting fees for the Thermalean and Lipodrene products. Significantly, the defendants' own expert identified NUG, NICWL, and Hi-Tech as among "five companies [that] have overlapping ownership and [which] incur costs and expenses in relation to [Thermalean, Lipodrene, and Spontane-ES]." Abernathy Expert Report, attached as Ex. 2 to Knight Decl. [Doc. No. 172, Ex. 7].

In addition, the companies worked together to develop and advertise their products. For example, in a related trademark infringement action, Hi-Tech alleges that it worked for years with now-dissolved United Metabolic Research Center, Inc. ("UMRC"), which it ultimately equates with NUG, to develop the original Lipodrene product.[8] Trademark Compl., ¶¶ 14-17,

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[7] Purportedly, Wheat reimbursed each company for the expenditures that it made on behalf of the other companies. However, it does not appear that the companies were compensated for the services that they performed on the other companies' behalf.

[8] Although Hi-Tech does not directly state that NUG and UMRC are the same entity, it essentially concedes this point over the course of its briefing. As noted above, Hi-Tech alleges in a related trademark infringement case that it and its self described "sister company," UMRC, spent years developing the original Lipodrene product. Trademark Compl., ¶¶ 14-17, attached as Ex. 1 to Knight Decl. [Doc. No. 195, Ex. 30]. Hi-Tech then states, in that complaint, that UMRC marketed the original Lipodrene through mail order until the product was reformulated. Id. at ¶ 17.

attached as Ex. 1 to Knight Decl. [Doc. No. 195, Ex. 30]. Hi-Tech goes on to represent that NUG/UMRC marketed the original Lipodrene through mail order until the product was reformulated. At that point, Hi-Tech, using some of the same advertising materials for the original Lipodrene, began to market the new Lipodrene through wholesale and retail outlets. Hi-Tech later used – almost verbatim – NICWL's Thermalean brochure to market its new Lipodrene. Similarly, HiTech also used claims, language, and artwork from NUG's Spontane-ES

Confusingly, in its brief in support of its motion for summary judgment [Doc. No. 170, Ex. 1, p. 11] and its corresponding statement of facts [Doc. No. 171, ¶ 25], Hi-Tech unambiguously asserts that Warner Laboratories, a division of NUG, marketed the original Lipodrene product and transmitted the income to NUG. This is consistent with the Lipodrene advertisements attached to the complaint, which reflect that Warner Laboratories was the generating entity [Doc. No. 1, Exs. C-E]. However, this is obviously inconsistent with Hi-Tech's allegations in the trademark infringement complaint and with Hi-Tech's expert's report, which notes that Lipodrene was produced, marketed, and sold by UMRC between January 1, 2001, and March 31, 2004. Abernathy Expert Report, attached as Ex. 2 to Knight Decl., at NUG 0006331 [Doc. No. 172, Ex. 7].

In the defendants' statement of disputed material facts [Doc. No. 198, ¶ 19], in which Hi-Tech joins, they again confuse the companies, this time noting that NUG sold the original Lipodrene product under the corporate name of Warner Laboratories, which they identify as a division of UMRC.

Finally, Hi-Tech begins to refer to NUG and UMRC as "NUG/UMRC" in its reply brief [Doc. No. 202, p. 5, n.3]. Similarly, Hi-Tech begins to use NUG and UMRC's names interchangeably throughout its Response to the FTC's Statement of Additional Facts [Doc. No. 202, Ex. 1]. If Hi-Tech cannot maintain any distinction between UMRC and NUG in its own briefs, then the court must conclude that the companies functioned as a single entity.

advertisement to market its male potency product, Stamina-RX.

When the operations of the companies are considered as a whole, it is clear that they functioned as a common enterprise. All were controlled by the same primary parties, all used and/or shared advertising generated by these controlling individuals, all worked together to achieve profitability, and all shared costs and expenses in relation to the same products. Most importantly, if one of these companies escaped liability, it would afford all three a means for continuing their operations. The few distinctions between the corporations (i.e., the fact that they maintained separate bank, merchant, and UPS accounts and filed their taxes separately) are superficial in nature and would not, when considered in light of the overwhelming evidence of the corporations' interrelated functions, provide a reasonable jury with a basis to reject the application of the common enterprise theory here. The evidence compels that the court find a common enterprise; thus, NUG, NICWL, and Hi-Tech should share liability for the advertisements at issue. Accordingly, Hi-Tech is not entitled to summary judgment here.

C. ***The Defendants' Motion for Summary Judgment [Doc. No. 168]***

The defendants' summary judgment argument is two-pronged. First, the defendants contend that the court should not use the FTC's standards in applying the FTC Act because it argues that those standards are unconstitutional. Second, the defendants contend that they are entitled to summary judgment because the FTC is not eligible for injunctive relief under Section 13(b) of the FTC Act. Because the

defendants have requested that the court consider their arguments regarding injunctive relief in the FTC's motion for summary judgment, the court will defer a discussion on these arguments until it addresses that motion. Accordingly, the court need only address the defendants' constitutional arguments at this juncture.

The defendants dedicate a large portion of their briefing to an argument that the FTC's standards in applying the FTC Act are unconstitutional. Using a test articulated in Central Hudson Gas & Electric Corporation v. Public Service Commission, 447 U.S. 557 (1980), the defendants argue that many of the standards that the FTC uses to determine whether advertising is deceptive violate the First Amendment. In addition, the defendants contend that the standards that the FTC uses to review advertisements for violations of the FTC Act are unconstitutionally vague and overbroad. The court will address these arguments separately below.

1. ***The Defendants' Central Hudson Arguments***

In Central Hudson, 447 U.S. 557 (1980), the Supreme Court articulated a four-part analysis for reviewing whether a regulation governing commercial speech violates the First Amendment. The court stated,

> At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine

> whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.

Id. at 566. Focusing on the last three elements of this analysis, the defendants claim that the following standards that the FTC uses in determining whether advertising is false or deceptive violate the First Amendment:

> • The FTC does not consider proof of intent to deceive or permit a good faith defense when an advertisement is challenged as deceptive;
>
> • The FTC relies on its own facial analysis of an advertisement, rather than extrinsic evidence of consumer perceptions, to determine what implicit claims an advertisement promotes;
>
> • The FTC has not promulgated a trade rule to define what misleading implications flow from specified product claims or descriptions, particularly with respect to advertising containing ingredient specific substantiation; and
>
> • The FTC requires all advertising claims that pertain to a supplement's health related benefits to be substantiated by competent and reliable scientific evidence but does not define "competent and reliable scientific evidence."

The court concludes that the defendants have misapplied the Central Hudson test in this situation. The test the Court articulated in Central Hudson was promulgated to assist courts in determining whether a

regulation that limits protected commercial speech is constitutional. Here, the defendants do not attack any particular regulation restricting speech; instead, the defendants attack the guidelines the FTC uses to determine whether speech is protected. See Bristol-Myers Co. v. FTC, 738 F.2d 554, 562 (2d Cir. 1984) ("[D]eceptive advertising enjoys no constitutional protection."). Thus, the defendants employ circular logic: they contend that the court must use the Central Hudson test – which only applies to protected speech – to determine whether or not speech is protected.

The court is unpersuaded by this confusing and illogical argument. Whether or not the advertisements are deceptive, and thus unprotected speech, is a matter that is in the sound discretion of the court. Kraft, Inc. v. FTC, 970 F.2d 311, 316 (7th Cir. 1992) (citing FTC v. Colgate-Palmolive Co., 380 U.S. 374, 385 (1965)) ("[T]he words 'deceptive advertising' set forth a legal standard that derives its final meaning from judicial construction."). Accordingly, the court finds that Central Hudson does not apply in this situation.

2. ***The Defendants' Vagueness and Overbreadth Challenges***

In addition to the Central Hudson concerns presented above, the defendants allege that the FTC's standards regulating advertising are vague and overbroad. As an initial matter, the defendants' arguments regarding the overbreadth doctrine are unsustainable. The Supreme Court has explicitly held that the overbreadth doctrine cannot be used to challenge regulations of commercial speech. Village of Hoffman Estates v. Flipside, 455 U.S. 489, 497 (1982) ("the over-breadth doctrine does not apply to commercial speech."). All of the standards challenged by the

defendants in this case concern commercial speech; accordingly, the overbreadth doctrine does not apply.

The defendants' vagueness challenges center around the standards the FTC uses to determine whether claims that an advertisement makes regarding health and/or safety are adequately substantiated. The FTC requires advertising claims that pertain to a health benefit to be substantiated by competent and reliable scientific evidence. The defendants argue that this standard is unconstitutionally vague because it does not provide sufficient certainty about the criteria the FTC uses to evaluate the scientific support for ingredient-specific claims,[9] does not establish requirements for size, duration, or protocol of a scientific study, does not provide any single fixed formula for the number or type of scientific studies required to substantiate a claim, and does not specify the proper mechanism for extrapolating results of a study.

The defendants' arguments are not persuasive. As the defendants point out, "A statute can be impermissibly vague for either of two independent reasons. First, if it fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits. Second, if it authorizes or even encourages arbitrary and discriminatory enforcement." Hill v. Colorado, 530 U.S. 703, 732 (2000). Here, the defendants have not demonstrated that the FTC's standard fails for either

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[9] As a preliminary matter, the court notes that whether the FTC s standards provide sufficient certainty about the criteria the FTC uses to evaluate the scientific support for ingredient-specific claims is not at issue here, as none of the claims targeted by the FTC are ingredient-specific.

of these reasons. "Competent and reliable scientific evidence" has been defined in various contexts, including in guidelines promulgated by the FTC, as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." Bureau of Consumer Protection, Federal Trade Commission, Dietary Supplements, An Advertising Guide for the Industry (2001), p. 9, attached as Ex. H to Defs.' Mot. for Summ. J. [Doc. No. 168]. The court can find no reason why this definition would not give people of ordinary intelligence a reasonable opportunity to understand what evidence is required to substantiate their health-related claims. Obviously, this definition is context specific and permits different variations on "competent and reliable scientific evidence" depending on what pertinent professionals would require for the particular claim made. Thus, the size, duration or protocol of a scientific study, the number or type of scientific studies required to substantiate a claim, and the proper mechanism for extrapolating results from studies will obviously vary from circumstance to circumstance depending upon the expert evidence presented. However, the standard by which these issues of fact are resolved is clear, and an advertiser can be reasonably certain of what substantiation will be required by conferring with appropriate professionals or experts. The fact that different scientific evidence is required for different claims impacting different products does not mean that the FTC can enforce its act arbitrarily; instead, it simply means that different claims require

different substantiation. As Judge Dimock wrote in his concurring opinion in United States v. Shackne, 333 F.2d 475, 488 (2nd Cir. 1964), "Statutes are not . . . void for vagueness because they raise difficult questions of fact. They are void for vagueness only where they fail to articulate a definite standard." Here the FTC has articulated a definite standard; accordingly, the issues of fact that it generates do not render it unconstitutionally vague.

The defendants have failed to demonstrate that the FTC's standards at issue in this case are unconstitutional and, thus, are not entitled to summary judgment on this issue.

D. ***The FTC's Motion for Summary Judgment [Doc. No. 172]***

In the FTC's motion for summary judgment, the FTC argues that it is entitled to summary judgment on all of its claims because the defendants' advertisements violate the FTC Act. The defendants respond to the FTC's motion by first asserting that the FTC is legally precluded from litigating its claims by the doctrines of res judicata and collateral estoppel. The defendants then argue the merits of the case, contending that the FTC does not have sufficient evidence to demonstrate that the advertising was false and misleading and that most of the challenged advertising was non-actionable puffery. The court will first address the defendants' affirmative defenses before turning to the merits of the case.

1. ***The Defendants' Affirmative Defenses***

The defendants allege that the doctrines of res judicata and collateral estoppel preclude the FTC's claims. Specifically, they argue that the Consent Decree

that the defendants entered into with the FDA resolved the claims and issues presented in the current action.

Collateral estoppel and res judicata are affirmative defenses. Fed. R. Civ. P. R. 8(c). Eleventh Circuit courts have held that the "failure to include an affirmative defense in the answer or have it included in the pre-trial order of the district court, which supersedes the pleadings, will normally result in waiver of the defense." Jackson v. Seaboard C.L.R. Co., 678 F.2d 992, 1012 (11th Cir. 1982); see also Palmer v. Braun. 376 F.3d 1254, 1257 n.2 (11th Cir. 2004) (finding that the defendant waived his affirmative defense when he failed to include it in either his answer or the pretrial order). While parties may raise the res judicata and collateral estoppel defenses in a summary judgment motion if the motion is filed in place of an answer, Concordia v. Bendekovic, 693 F.2d 1073, 1075 (11th Cir. 1982), or if events subsequent to the filing of the answer give rise to the defenses and the assertion of the defenses is not prejudicial to the plaintiff, In re Air Disaster at Brunswick, Georgia, 879 F. Supp. 1196, 1200 (N.D. Ga. 1994), a party may not revive an available defense that he failed to assert in his answer by arguing it on summary judgment. Funding Systems Leasing Corp. v. Pugh, 530 F.2d 91, 96 (5th Cir. 1976).[10] This is consistent with Supreme Court rulings, which hold that preclusion defenses must be asserted in a timely manner. Arizona v. California. 530 U.S. 392, 410 (2000).

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[10] Decisions of the former Fifth Circuit issued prior to October 1, 1981, are binding precedent on this court. See Bonner v. City of Prichard, 661 F.2d 1206, 1207 (11th Cir. 1981).

In this case, the defendants base their preclusion defenses on a Consent Decree that they entered into with the FDA on September 22, 2003. Although the Consent Decree had been in place for almost sixteen months, the defendants did not assert res judicata or collateral estoppel when they filed their answers on January 18, 2005.[11] In fact, it was not until the defendants filed their response to the FTC's motion for summary judgment on November 5, 2007 – over four years after the Consent Decree was signed – that the defendants raised these preclusion defenses.

The court finds the defendants' delay in asserting these defenses inexcusable. The preclusion defenses that the defendants now attempt to assert have been available to them throughout the three plus years that this case has been pending. The defendants cannot assert them at this late point simply because the "light finally dawned" that they might be available. Arizona v. California, 530 U.S. at 410 ("We disapprove of the notion that a party may wake up because a 'light finally dawned,' years after the first opportunity to raise a defense, and effectively raise it so long as the party was (though no fault of anyone else) in the dark until its late awakening."). Accordingly, this court concludes that the defendants have waived their right to assert these defenses.

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[11] The defendants did attempt to reserve the right to assert additional defenses that became apparent during discovery; however, the court struck this "reservation of rights" defense in its June 24, 2005, order and noted that "absent permission of the court, the defendants are required to assert every defense in their answer." [Doc. No. 75, pp. 34-35].

2. ***Analysis of the Defendants' Advertisements for False and Misleading Claims***

As noted above, the FTC has asserted that the defendants violated Sections 5 and 12 the FTC Act by (1) making false claims regarding Thermalean, Lipodrene, and Spontane-ES; (2) making unsubstantiated claims regarding Thermalean, Lipodrene and Spontane-ES; and (3) making false claims regarding research and medical facilities. The FTC has also alleged that Dr. Wright violated the FTC Act by making false and unsubstantiated claims in his role as an expert endorser for Thermalean.

The court will first address the legal framework for analyzing the advertisements for violations of the FTC Act and then will apply that framework to the advertisements at issue. Finally, the court will address the defendants' defense that much of the advertising constitutes non-actionable puffery.

a. *Overview of the Law*

The FTC's claims are premised on the defendants' alleged violations of Sections 5 and 12 of the FTC Act. Section 5 of the FTC Act prohibits unfair or deceptive acts or practices in or affecting commerce. 15 U.S.C. § 45(a). Section 12 addresses false advertising and provides that the dissemination of false advertisements – defined as advertisements that are misleading in a material respect – is an unfair or deceptive practice in commerce. 15 U.S.C. §§ 52(b) and 55. "Thus, a violation of Section 12, dissemination of false advertising, constitutes a violation of Section 5(a)." FTC v. OT, Inc., 448 F. Supp. 2d 908, 957 (N.D. 111. 2006).

To establish liability under Sections 5 and 12 of the FTC Act, the FTC must prove: (1) that there was a

representation; (2) that the representation was likely to mislead customers acting reasonably under the circumstances; and (3) that the representation was material. FTC v. Tashman, 318 F.3d 1273, 1277 (11th Cir. 2003); see also Kraft, Inc., 970 F.2d at 314 (citing Sections 5 and 12 to state that "an advertisement is deceptive under the Act if it is likely to mislead customers, acting reasonably under the circumstances, in a material respect"); OT, Inc., 448 F. Supp. 2d at 957 (using this three part test to find violations of Sections 5 and 12). The court will address each of these elements in depth.

i. ***Was the Representation Made?***

The first step that the court must take to analyze whether the defendants violated the FTC Act is to determine whether the advertisements made the claims asserted by the FTC in the complaint. OT, Inc., 448 F. Supp. 2d at 957. The meaning of an advertisement, the claims or net impressions communicated to reasonable consumers, is fundamentally a question of fact. See, e.g., id. at 957-58 (citing National Bakers Services, Inc., v. FTC, 329 F.2d 365, 367 (7th Cir. 1964)). This question of fact may be resolved by the terms of the advertisement itself or by evidence of what consumers interpreted the advertisement to convey.

When assessing the meaning and representations conveyed by an advertisement, the court must look to the advertisement's overall, net impression rather than the literal truth or falsity of the words in the advertisement. FTC v. Peoples Credit First, LLC, No. 8:03-cv-2353-T-TBM, 2005 U.S. Dist. LEXIS 38545, at *20-25 (M.D. Fla. Dec. 18, 2005) (finding that an advertisement was implicitly deceptive by looking at

the net impression that it was likely to make on the general public). If the advertisement explicitly states or clearly and conspicuously implies a claim, the court need not look to extrinsic evidence to ascertain whether the advertisement made the claim. See In re Thomson Med. Co., Inc., 104 F.T.C. 648, 311-12 (1984) (noting that when an advertisement unequivocally states a claim, "it is reasonable to interpret the ads as intending to make [it]"); OT, Inc., 448 F. Supp. 2d at 958 ("Where implied claims are conspicuous and reasonably clear from the face of the advertisements, extrinsic evidence is not required.") (internal citations omitted). However, if the advertisement faintly implies a claim, the court may certainly decline from concluding that the advertisement makes such a representation without extrinsic evidence of consumer perceptions. As another district court noted, "implied claims fall along a continuum from those which are so conspicuous as to be virtually synonymous with express claims to those which are barely discernable. It is only at the latter end of the continuum that extrinsic evidence is necessary." FTC v. Febre, C.A. No. 94-C-3625, 1996 U.S. Dist. LEXIS 9487, at *14-15 (N.D. 111. July 2, 1996).

In this case, the FTC has not presented any evidence of what claims consumers perceived the advertisements to make; accordingly, any claims that the FTC contends that the advertisements make must be clear and conspicuous from the face of the advertisements.[12]

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[12] Despite established case law to the contrary, the defendants argue that the court "cannot reliably or accurately ascertain the meaning of the advertisements." Defs.' Resp. Br., p. 33 [Doc. No. 196]. Citing the FTC's expert's testimony, the defendants contend that

ii. *Is the Representation Likely to Mislead?*

To demonstrate that a claim is likely to mislead a reasonable customer, the FTC may proceed under a "falsity theory," a "reasonable basis theory," or both. OT, Inc., 448 F. Supp. 2d at 957-58. If the FTC proceeds under a falsity theory, it "must demonstrate either that the express or implied message conveyed by the ad is false." FTC v. Natural Solutions, Inc., C.A. No. 06-6112-JFW, 2007 U.S. Dist. LEXIS 60783, at *10 (CD. Cal. Aug. 7, 2007). If the FTC proceeds under a "reasonable basis" theory, it must demonstrate that the advertiser lacked a reasonable basis – or adequate substantiation – for asserting that the message was true. Id. As discussed in the defendants' motion for summary judgment, in the case of health-related claims or claims concerning the efficacy or safety of dietary supplements, this reasonable basis must, at a minimum, consist of competent and reliable scientific evidence. OT, Inc., 448 F. Supp. 2d at 961.

All of the products at issue in this case are dietary supplements and/or drugs that are marketed as promoting health benefits in the form of weight loss

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only the recipients of the advertising can ascertain the content and meaning of the advertisements and the claims which influenced their purchase decision. Id. at pp. 32-33.

The court is not persuaded by the defendants' argument. As the above case law indicates, the court is well-equipped to discern express claims or clear and conspicuous implied claims from the face of the advertisement. While evidence of consumer perceptions is always welcomed by the court, it is only necessary when the asserted claims fall on the "barely discernable" side of the continuum. The court concludes that imposing a legal requirement on the FTC to survey the exact consumer group that the defendants solicited is both unduly burdensome and unnecessary, particularly when the claims are apparent from the face of the advertisement.

and sexual enhancement. Not surprisingly, all of the unsubstantiated representations that the FTC claims the advertisements make are related to the safety and/or efficacy of the dietary supplements and, correspondingly, implicate health concerns. Thus, all of the lack of reasonable basis claims discussed in this case must be supported by "competent and reliable scientific evidence."

As noted in the discussion of the defendants' motion for summary judgment [Doc. No. 168], the FTC has defined competent and reliable scientific evidence as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." Dietary Supplements, An Advertising Guide for the Industry, supra, at 9. The court adopts this definition. Thus, what constitutes competent and reliable scientific evidence in this case is a question of fact for expert interpretation. Id.

iii. ***Is the Representation Material?***

"A representation or omission is material if it is the kind usually relied on by a reasonably prudent person." FTC v. Windward Marketing, No. 1:96-cv-615, 1997 U.S. Dist. LEXIS 17114, at *27 (N.D. Ga. Sept. 30, 1997); see also OT, Inc., 448 F. Supp. at 960 ("A claim is considered material if it involves information that is important to consumers and, hence, likely to affect their choice of, or conduct regarding, a product.") (internal citations omitted). "Express claims, or deliberately made implied claims, used to induce the purchase of a particular product or service are presumptively material." Windward Marketing, 1997

U.S. Dist. LEXIS 17114, at *28. In addition, other courts have also found claims that "significantly involve health, safety, or other issues that would concern reasonable customers" to be presumptively material. OT, Inc., 448 F. Supp. 2d at 960, 965-66.[13]

As noted above, all of the representations that the FTC claims the ads make are related to health and/or safety. As a matter of practicality, this court finds it hard to imagine that any reasonable customer would find claims regarding how a product affects his or her health or safety immaterial, but the court need not reach that question at this juncture. For purposes of this case, it is sufficient to state that when a customer makes a decision to purchase a health product that he or she will ingest for purported health benefits, any claim on the label regarding the health benefits (i.e., any product efficacy claims) or any claims regarding the safety of the product can be presumed material. Thus, the court will presume that all of the asserted claims in this case, if made, were material to the customers' purchasing decisions.

b. ***Application of the Law to Product Claims and False Endorsement Claims***

The FTC asserts that the defendants' advertising violates the FTC Act by making false and unsubstantiated claims regarding Thermalean, Lipodrene, and Spontane-ES. The FTC also alleges that

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[13]As both OT, Inc. and Windward Marketing suggest, the court may presume that some claims are material absent evidence to the contrary. The defendants' argument that the court may not ascertain the materiality of such claims is unavailing and contradicted by the cited case law.

Dr. Wright made false claims and claims without a reasonable basis in his endorsement of Thermalean. The court will examine the advertisements on a product-by-product basis to determine whether the claims were made. The court will then address (1) whether the claims are likely to mislead a reasonable consumer; and (2) whether the claims are material.

i. ***Do the Advertisements Make the Claims?***

(A) ***Thermalean Claims and Wright False Endorsement Claims***

As a basis for its allegations, the FTC attached to the complaint a nine-page Thermalean brochure and a two-page letter "from the desk of Dr. Mark Wright, M.D., Chief of Staff, NICWL" ("the Wright letter") endorsing Thermalean. [Doc. No. 1, Exs. A and B]. Based on these advertisements, the FTC has asserted that the defendants made the following false and deceptive claims:

Falsity Claim 1: Thermalean is clinically proven to be an effective treatment for obesity;

Falsity Claim 2: Thermalean causes rapid and substantial weight loss, including as much as 30 pounds in 2 months;

Falsity Claim 3: Thermalean is clinically proven to cause rapid and substantial weight loss, including as much as 30 pounds in 2 months;

Falsity Claim 4: Thermalean is clinically proven to enable users to lose 19% of their total body weight, lose 20-35% of abdominal fat, reduce their overall fat by 40-70%, decrease their stored fat by 300%, and increase their metabolic rate by 76.9%; and

Falsity Claim 5: Thermalean is clinically proven to inhibit the absorption of fat, suppress appetite, and

safely increase metabolism without dangerous side effects.

Compl., ¶¶ 21-22 [Doc No. 1]. The FTC has also asserted that the defendants made the following representations ("Lack of Reasonable Basis ("LORB") Claims") without possessing or relying upon a reasonable basis to substantiate the claims:

LORB Claim 1: Thermalean is an effective treatment for obesity;

LORB Claim 2: Thermalean causes rapid and substantial weight-loss, including as much as 30 pounds in two months;

LORB Claim 3: Thermalean causes users to lose 19% of their total body weight, lose 20-35% of abdominal fat, reduce their overall fat by 40-70%, decrease their stored fat by 300%, and increase their metabolic rate by 76.9%;

LORB Claim 4: Thermalean inhibits the absorption of fat, suppresses appetite, and safely increases metabolism without dangerous side effects;

LORB Claim 5: Theramalean is equivalent or superior to the prescription weight loss drugs Xenical, Meridia, and Fastin in providing weight loss benefits; and

LORB Claim 6: Thermalean is safe.

Id. at ¶¶ 23-24. In addition, the FTC has used the two Thermalean advertisements as the basis for its expert endorsement claims against Dr. Wright. The FTC asserts that Dr. Wright made the following false endorsements regarding Thermalean:

False Endorsement Claim 1: Thermalean is clinically proven to be an effective treatment for obesity;

False Endorsement Claim 2: Thermalean is clinically proven to cause rapid and substantial weight loss, including as much as 30 pounds in two months;

False Endorsement Claim 3: Thermalean is clinically proven to enable users to lose 20-35% of abdominal fat, reduce their body fat by 42%, decrease their stored fat by 300%, and increase their metabolic rate by 76.9%; and

False Endorsement Claim 4: Thermalean is clinically proven to inhibit the absorption of fat, suppress appetite, and safely increase metabolism without dangerous side effects.

Id. at ¶¶ 34-35. The FTC also claims that Dr. Wright made the following claims without a reasonable basis:

Wright LORB Claim 1: Thermalean is an effective treatment for obesity;

Wright LORB Claim 2: Thermalean causes rapid and substantial weight loss, including as much as 30 pounds in 2 months;

Wright LORB Claim 3: Thermalean causes users to lose 20-35% of abdominal fat, reduce their body fat by 42%, decrease their stored fat by 300%, and increase their metabolic rate by 7 6.9%;

Wright LORB Claim 4: Thermalean inhibits the absorption of fat, suppresses appetite, and safely increases metabolism without dangerous side effects;

Wright LORB Claim 5: Thermalean is equivalent or superior to the prescription weight loss drugs Xenical, Meridia, and Fastin in providing weight loss benefits; and

Wright LORB Claim 6: Thermalean is safe.

The court will analyze the advertisements for each of these claims. Where the claims are closely

linked and supported by the same or similar evidence, the court will examine the claims in tandem.

(1) Falsity Claim 1, LORB Claim 1, False Endorsement Claim 1, and Wright LORB Claim 1

The FTC argues that the advertisements and Dr. Wright falsely represent that Thermalean is clinically proven to be an effective treatment for obesity and represent, without a reasonable basis, that Thermalean is an effective treatment for obesity. The court has surveyed the advertisements, and has identified the following express statements related to obesity:

• Introducing Thermalean (575 mg Capsule) [-][t]hree specific causes linked to obesity with one solution Thermalean [Doc. No. 1, Ex. A-2];

• At the National Institute for Clinical Weight Loss, [o]ur research and development team has developed a non-prescription formulation that incorporates a naturally occurring equivalent and substitute for Meridia, Xenical, and Fastin.[14] Thermalean is the most complete, omni-faceted nutriceutical ever developed for the diet industry! After four full years of product development and feedback from hundreds of thousands of clients, we are very proud to announce that Thermalean is the **FIRST** over-the-counter (OTC) nutriceutical to incorporate all three aspects of obesity into one amazing product called Thermalean [*Id.*];

• Why Thermalean? Why now? Thermalean is a product of decades of research and development in the field of weight loss. Thermalean was designed to help the person only needing to los[e] 5 or 10 pounds, as well as the person needing to lose 100 or more pounds.

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[14] These three products are identified earlier in the advertisement as pharmaceuticals that each "address one aspect of obesity." [Doc. No. 1, Ex. A].

Pharmaceutical "mega-firms" would have you believe that their product is the only product to fight obesity. If this were true then why is America the most overweight society in the history of the world? With an estimated 75 million Americans clinically considered obese the question should be, Why not now? [Doc. No. 1, Ex. A-7];

• With 75 million Americans clinically considered "obese" [sic] Thermalean could not have come at a better time [Doc. No. 1, Ex. A-6, Wright Endorsement Section];

• Try Thermalean today and win the battle against obesity [Wright Letter, Doc. No. 1, Ex. B-2].

After reviewing these express statements in light of the advertisements in full, the court is persuaded that the defendants' advertisements, including Dr. Wright's endorsement, clearly imply that Thermalean is an effective treatment for obesity. However, the court is not convinced that the advertisements clearly and conspicuously imply that Thermalean is *clinically proven* to treat obesity. Throughout the advertisements, the defendants heavily imply that Thermalean is clinically proven to cause weight loss. However, the defendants have presented evidence that the disease of obesity is different from general weight loss; thus, the court will not presume, without extrinsic evidence, that a recipient of these advertisements would infer that Thermalean is clinically proven to treat obesity from the clinical weight loss claims. Since the FTC has presented no extrinsic evidence, the court concludes that the advertisements do not represent that Thermalean is clinically proven to treat obesity and thus do not make Falsity Claim 1 or False Endorsement Claim 1.

(2) Falsity Claims 2 and 3. LORB Claim 2, Wright False Endorsement Claim 2 and Wrioht LORB Claim 2

The FTC contends that the Thermalean advertisements and defendant Wright as an endorser falsely and without a reasonable basis represent that Thermalean causes rapid and substantial weight-loss, including as much as 30 pounds in two months. In addition, the FTC contends that the advertisements and Wright falsely represent that Thermalean is clinically proven to cause rapid and substantial weight-loss, including as much as 30 pounds in two months. The court has reviewed the advertisements, and concludes that they, through Wright's endorsements, make the asserted representations. The Wright letter states, "Thermalean is the most complete product on the market today for rapid[,] sustainable weight loss . . . Whether you need to lose 10, 20, 100 pounds or more, Thermalean will work for you." [Doc. No. 1, Ex. B]. Obviously, this portion of the letter expressly states that Thermalean delivers fast, significant weight loss. However, the court need not hang its hat on this statement alone, as the brochure also unambiguously makes the claims at issue here. In the "Questions for Dr. Mark Wright, M.D." portion of the brochure, the advertisement states:

> Q: How much weight can I expect to lose with Thermalean?
>
> A: Clinical trials based on Thermalean's proprietary components have yielded weight loss to nearly 15% of beginning body weight within the first two months

Example: (to put this statistic in perspective)

Starting Date	June 1
Starting Weight	200 lbs
Weight after 60 days	170 lbs
Weight loss in 60 days	30 lbs

[Doc. No. 1, Ex. A].

This question and answer segment establishes that Thermalean causes rapid, significant weight loss, and the example given indicates that a consumer can lose up to thirty pounds in two months. In addition, the answer is purportedly based on "clinical trials," providing support for the falsity claims at issue here.[15] Although the defendants have highlighted the language regarding "proprietary components" and argued that the clinical trials and the results thereof were explicitly referring to the ingredients rather than the product as a whole, the court is not persuaded by this argument. The question part of the segment asks about the overall Thermalean product, and the answer, though phrased as an answer regarding the proprietary components, was clearly meant to respond to the query regarding the benefits of the product as a whole. The advertisement's generic reference to "Thermalean's

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[15] Confusingly, the defendants' expert, Dr. Richey, indicated in his report that study participants who were shown a copy of the Lipodrene and Thermalean advertisements did not feel that the marketer did a clinical test. However, in parentheses beside this statement, Dr. Richey indicates that the average participant slightly agreed with the statement, "The company who developed this advertisement did a clinical test of this specific branded product." [Doc. No. 198, Ex. 7, pp. 7 and 35]. Because the court concludes that no reasonable consumer would rely upon an expert's conclusion that is directly contradicted by the expert's own study results, the court will disregard this evidence.

proprietary components" emphasizes not the unnamed ingredients but the overall product, and thus achieves the advertisement's goal of promoting the product the defendants are attempting to sell. The unambiguous intent and meaning of the advertisement is that Thermalean – not its "proprietary components" – causes rapid and substantial weight loss, including as much as thirty pounds in two months; thus, the court concludes that the advertisements make the representations alleged by the FTC.[16]

(3) Falsity Claim 4 and LORB Claim 3

The FTC asserts that the advertisements falsely convey that Thermalean is clinically proven to enable

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[16] In their brief, the defendants cite a survey conducted by their expert for the proposition that "consumer intent to purchase the products at issue was driven by the claims in the advertisements about the ingredients of the product and not the product itself." [Doc. No. 196, p. 37]. The court notes that even if this statement was supported by the evidence, it pertains to the materiality of claims rather than the question of whether claims were made. However, the portions of the study upon which this statement is based do not provide a foundation for the statement. The study simply reflects that participants mildly agreed with the following statements:

(1) I am able to think systematically about information that is given to me about a product, and make my own judgments about the effectiveness of a product; and

(2) I believe that information about the components of a product is useful to me when deciding whether or not to purchase the product.

Richey Report, p. 13 [Doc. No. 198, Ex. 7]. In the survey results, the court can find no basis for the expert's cited conclusion that consumer intent to purchase the products at issue was not driven by claims about the products themselves.

users to lose 19% of their total body weight, lose 20-35% of abdominal fat, reduce their overall fat by 40-70%, decrease their stored fat by 300%, and increase their metabolic rate by 7 6.9%. The FTC also asserts that the advertisements, without a reasonable basis, represent that Thermalean causes users to accomplish these same statistical results.

> The Thermalean brochure states,
>
> Clinical studies show the active components in Thermalean yield the following extraordinary results:
>
> Loss of 19% total body weight
>
> Increase metabolic rate by 76.9% without exercise
>
> Reduction of 40-70% overall fat under the skin
>
> Loss of 20-35% of abdominal fat.

[Doc. No. 1, Ex. A-2].

> Similarly, the brochure also states,
>
> In their precise ratios, the thermogenic components used in Thermalean have achieved the following results in University-sponsored clinical trials (all of these statistics have been reported in such professional journals as the International Journal of Obesity, American Journal of Clinical Nutrition, and The New England Journal of Medicine):
>
> - 300% decrease in stored fat vs. placebo
> - 29% greater weight loss vs. REDUX
> - 600% increase in total weight loss vs. placebo
> - 42% reduction in body fat in a specified time period

Id. at A-3.

A quick analysis of the language above demonstrates that the Thermalean brochure conveys the asserted claims. The brochure unequivocally states that Thermalean's "active components" and "thermogenic components" enable users to lose 19% of their total body weight, lose 20-35% of abdominal fat, reduce their overall fat by 40-70%, decrease their stored fat by 300%, and increase their metabolic rate by 76.9%. It also unequivocally represents that these results are backed by clinical studies and independent, university-sponsored clinical trials. Although the defendants go to great lengths to establish that this express language is language about the ingredients rather than language about the Thermalean product, the court is not persuaded by such meaningless distinctions. The brochure does not define these active and/or thermogenic components by name or proportion; instead, it simply uses these references to mysterious ingredients as synonyms for "Thermalean." The obvious implication from the brochure is that Thermalean – as a whole – is scientifically and clinically proven to yield the touted results; accordingly, the court concludes that it makes the alleged claims.

(4) Wright False Endorsement Claim 3 and Wright LORB Claim 3

The FTC also contends that Dr. Wright, without a reasonable basis, represents that Thermalean causes users to lose 20-35% of abdominal fat, reduce their body fat by 42%, decrease their stored fat by 300%, and increase their metabolic rate by 7 6.9%. In addition, the FTC contends that Dr. Wright falsely represents that

Thermalean is clinically proven to cause users to achieve these same results.

Under the "Questions for Dr. Mark Wright, M.D." section, the Thermalean brochure states, "Thermalean's scientifically proven formula has yielded the following results in independent university-sponsored trials: 42% reduction in body fat - 300% decrease in stored fat - 76.9% elevation in basal metabolic rate - 20-35% reduction in abdominal fat - 600% greater fat burning capabilities than placebo." Id. at A-6. This language almost explicitly states that Thermalean causes users to achieve a 20-35% loss of abdominal fat, a 42% reduction in total body fat, a 300% decrease in stored fat, and a 76.9% increase in metabolic rate. Although this portion of the brochure does not specifically state that Thermalean has been *clinically* proven to yield these results, it does state that Thermalean is a scientifically proven formula that has yielded the desired results in independent university-sponsored trials. The court concludes that this language clearly implies that the results were "clinically proven," and is satisfied that Wright made both of the asserted claims.

(5) Falsity Claim 5. LORB Claims 4 and 5, Wright False Endorsement Claim 4. and Wright LORB Claims 4 and 5

The FTC claims that Dr. Wright and the advertisements falsely represent that Thermalean is clinically proven to inhibit the absorption of fat, suppress appetite, and safely increase metabolism without dangerous side effects. In addition, the FTC claims that the advertisement and Wright, without a reasonable basis, represent that Thermalean inhibits the absorption of fat, suppresses appetite, and safely

increases metabolism without dangerous side effects. Because the advertising language supporting these claims also supports the representation that Thermalean is equivalent or superior to the prescription weight loss drugs Xenical, Meridia, and Fastin in providing weight loss benefits, all claims will be discussed together.

On the second page, the Thermalean brochure states:

> The pharmaceutical drugs Xenical, Meridia, and Fastin all address one aspect of obesity and only one aspect:
> 1.) Xenical Inhibits the absorption of dietary fats
> 2.) Meridia Suppresses the appetite by blocking the re-uptake of serotonin
> 3.) Fastin Burns fat by increasing the metabolic rate
>
> Each of these novel pharmaceuticals attack one aspect of obesity, but neglect to address the other causes of obesity.
>
> At the National Institute for Clinical Weight Loss, Our research and development team has developed a non-prescription formulation that incorporates a naturally occurring equivalent and substitute for Meridia, Xenical, and Fastin. Thermalean is the most complete, omni-faceted nutriceutical ever developed for the diet industry! After four full years of product development and feedback from hundreds of thousands of clients, we are very proud to

> announce that Thermalean is the **FIRST** over the counter (OTC) nutriceutical to incorporate all three aspects of obesity into one amazing product called Thermalean and the results have been extraordinary - without side effects!

[Doc. No. 1, Ex. A-2]. Similarly, Dr. Wright's letter states, "Thermalean is a pharmaceutical-grade nutriceutical containing naturally occurring equivalents and substitutes for Sibutramine (Meridia), Orlistat (Xenical), and Phentermine (Fastin) in Thermalean's Core Pharmaceutical Composition and Formulation." Id. at Ex. B 1. A few paragraphs down, the letter goes on to state,

> Thermalean's proprietary components have been proven to accomplish the following:
>
> Inhibit Lipase for obesity management by inhibiting the absorption of dietary fats.
>
> Slows the rate at which the body "metabolizes" serotonin therefore suppressing the appetite.
>
> Safely increasing the metabolic rate without dangerous side-effects associated with prescription drugs.
>
> Thermalean was engineered upon cutting-edge scientific and clinical data which supports our claim that Thermalean is unmatched by any other prescription or non-prescription diet aid currently available.

Id. The above language clearly supports the claim that Thermalean is equivalent or superior to Meridia, Xenical, and Fastin and the claim that Thermalean inhibits the absorption of fat, suppresses appetite, and safely increases metabolism without dangerous side effects.[17] The court also finds that the advertisements represent that Thermalean is *clinically proven* to inhibit fat absorption, suppress appetite, and increase metabolism. The Wright letter is printed on National Institute for Clinical Weight Loss letterhead and claims to be "From the desk of: Dr. Mark Wright M.D. Chief of Staff, NICWL." Id. The letter states that Thermalean's proprietary components have been proven to accomplish the functions that are the subject of these claims. Id. Immediately beneath this statement, the letter states that Thermalean was engineered upon cutting-edge scientific and clinical data. Id. These different components, when read as a whole, create the impression that Thermalean was proven to accomplish the asserted functions through clinical studies and/or trials. Moreover, the brochure repeatedly emphasizes that Thermalean achieves clinically proven weight loss by blocking the absorption of dietary fats, suppressing the appetite, and increasing the metabolism. This creates the impression that Thermalean has been clinically proven to achieve its three touted functions.

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[17] Although the Wright letter incorporates the use of the term "proprietary components," the court is not persuaded by the defendants' arguments that the statement refers to Thermalean's individual ingredients rather than the product as a whole. As previously noted, the generic reference to all of a product's ingredients, without more, essentially functions as a synonym for the product's name.

(6) LORB Claim 6 and Wright LORB Claim 6

Finally, the FTC claims that the Thermalean advertisements and Dr. Wright represent that Thermalean is safe without adequate substantiation. For this claim, the court need look no further than the express language of the advertisements. For example, the Thermalean brochure states, "New Thermalean is safe and natural" and "New Safe Alternative Just Released - Thermalean." [Doc. No. 1, Ex. A-8]. Likewise, the Wright letter states "the introduction of Thermalean reflects the cumulative efforts of many top bariatric (weight loss) physicians and researchers to bring the public a safe and effective, scientifically based formulation that will have a significant impact on your weight loss goals." Id. at Ex. B-2. Because the advertisements and Dr. Wright expressly state that Thermalean is safe, no additional analysis is necessary.

(B) Lipodrene Claims

The FTC attached three Lipodrene advertisements as exhibits to the complaint. The first exhibit is a one-page advertisement placed in Cosmopolitan Magazine that states – in large, underlined letters across the top – "Clinically PROVEN Weight Loss." [Doc. No. 1, Ex. C]. The second exhibit is a more detailed, two-page direct mail insert prepared on Warner Laboratories letterhead that provides an overview of Lipodrene's Phase I Review and announces the launch of Phase II. Id. at Ex. D. The third exhibit attached to the complaint is a one-page print of an internet web page. Id. at Ex. E. It clearly refers to Lipodrene, and states in prominent print, "Clinically PROVEN to be SAFE AND EFFECTIVE!" Id.

Based on the these advertisements, the FTC contends that the defendants made the following false claims:

Falsity Claim 1: Lipodrene causes weight loss, including as much as 125 pounds;

Falsity Claim 2: Lipodrene is clinically proven to enable users to lose up to 42% of total body fat and 19% of total body weight, and to increase their metabolic rate by up to 50%;

Falsity Claim 3: Lipodrene is clinically proven to be safe; and

Falsity Claim 4: Lipodrene is clinically proven to cause virtually no side effects.

[Doc. No. 1, 55 25-26]. In addition, the FTC also argues that the defendants made the following representations regarding Lipodrene without adequate substantiation:

LORB Claim 1: Lipodrene causes substantial weight loss, including as much as 125 pounds;

LORB Claim 2: Lipodrene enables users to lose up to 42% of total body fat and 19% of total body weight, and to increase their metabolic rate by up to 50%; and

LORB Claim 3: Lipodrene is safe.

Id. at 55 25-26. Each of these claims will be discussed below.

(1) Falsity Claim 1 and LORB Claim 1

The FTC claims that the Lipodrene advertisements falsely and without a reasonable basis represent that Lipodrene causes substantial weight loss, including as much as 125 pounds. The court has reviewed the advertisements and concludes that the first advertisement does make the asserted representation. First, the advertisement clearly represents that

Lipodrene causes substantial weight loss. Directly beneath the "Clinically PROVEN Weight Loss!" banner at the top of the page, the ad states: "Lose up to 42% of your total body fat! Lose up to 19% of your total body weight!" [Doc. No. 1, Ex. C]. Underneath this segment, the ad touts an overall 88% success rate. Id. The court concludes that, when read together, this ad suggests that Lipodrene is a tried and tested way to lose substantial weight – even up to 19% of one's total body weight. However, the advertisement does not stop with these assertions. The ad, in a section "*from Dr. Mark Wright, M.D. – Medical Director for Warner Laboratories,*" states, "Lipodrene is a product you simply MUST TRY if you are having trouble losing weight – whether your weight loss goals involve 5 lbs, 25 lbs, or even 125 lbs." Id. This statement from a doctor clearly implies that Lipodrene can help patients meet their weight loss goals – even if that goal is 125 pounds. Accordingly, the court finds that the advertisement makes the asserted representation.[18]

(2) Falsity Claim 2 and LORB Claim 2

The FTC contends that the Lipodrene advertisements falsely represent that Lipodrene is clinically proven to enable users to lose up to 42% of their total body fat and 19% of their total body weight and to increase their metabolic rate by up to 50%. In addition, the FTC contends that the Lipodrene advertisements, without a reasonable basis, represent

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[18] The other two advertisements do not contain any language specifying 125 pounds, but they do expressly claim that Lipodrene causes significant weight loss. Each of the advertisements note that Lipodrene can reduce a consumer's total body fat by 42% and total body weight by 19%. Thus, this court finds that they provide additional support for the asserted claim.

that Lipodrene enables users to accomplish these goals. All three of the advertisements contain language indicating that Lipodrene enables users to accomplish these asserted statistical goals and that such results are clinically proven. For example, the first advertisement sandwiches statements that a consumer can "Lose up to 42% of your total body fat! Lose up to 19% of your total body weight! Increase your metabolic rate up 50%!" directly underneath a "Clinically proven weight loss" banner and directly beside a segment that states that "Lipodrene technology is backed by volumes of Independent Research and hundreds of published studies by the most prominent Universities and Medical Journals in the world." [Doc. No. 1, Ex. C]. When read in context, the only logical conclusion is that these statistical representations have clinical and scientific support.

The court need not even engage in an analysis of the second advertisement, because that ad, citing Warner Laboratories' Chief of Staff, Dr. Timothy Gaginella, explicitly states that the Lipodrene technology accomplished the statistical results in clinical trials. [Doc. No. 1, Ex. D-2].

The third advertisement is much like the first advertisement in that it squeezes these statistical results beneath a larger statement that Lipodrene is "Clinically PROVEN to be SAFE AND EFFECTIVE!" and above a segment that states, "The Lipodrene technology is backed by Volumes of Independent Research and hundreds of Published studies by the most prominent Universities and Medical Journals in the world . . . ." [Doc. No. 1, Ex. E]. As was the case with the first ad, this positioning conveys the impression that Lipodrene is clinically

proven to accomplish the ambitious statistical results set forth therein.

(3) Falsity Claim 3 and LORB Claim 3

The FTC asserts that the Lipodrene advertisements represent that Lipodrene is clinically proven to be safe or, more simply, that Lipodrene is safe. To find these claims, the court need look no further than the express language in the short, one-page internet print out attached to the complaint that states, in reference to Lipodrene, "**Clinically PROVEN to be SAFE AND EFFECTIVE?**" [Doc. No. 1, Ex. E]. As this language is expressly stated, no further analysis is needed.

(4) Falsity Claim 4

The FTC asserts that the advertisements falsely represent that Lipodrene is clinically proven to cause virtually no side effects. Under a header entitled Lipodrene: PHASE I REVIEW, the first advertisement states, "Upon review of 25,000 participants in the Phase I trials, Lipodrene has been shown to yield an 88% SUCCESS RATE with virtually no side effects." [Doc. No. 1, Ex. C]. As previously discussed, this advertisement begins with the "Clinically PROVEN weight loss" banner and contains a caption noting that the Lipodrene technology is backed by volumes of respected studies and research. Id. In the second advertisement, the ad recaps the Phase I results and notes that there was "an extremely low incidence of side effects." Id. at Ex. D-2. The advertisement further cites Dr. Gaginella for the observation that Lipodrene appears to be void of significant or problematic side effects. Id. The third advertisement, as just discussed, contains the statement

that Lipodrene is "[c]linically PROVEN to be SAFE AND EFFECTIVE!" Id. at Ex. E.

Although none of these advertisements expressly state that Lipodrene is clinically proven to have virtually no side effects, the claim that Lipodrene is "clinically proven to be safe" in the third ad heavily implies that clinical studies have shown that Lipodrene has no or negligible side effects. Id. at Ex. E. Moreover, the second ad, which involves a doctor ratifying Lipodrene because of its "near-negligible rate of side effects," heavily implies some sort of clinical backing. Id. at Ex. D-2. Finally, both the first and second advertisements attribute side-effect claims to the mysterious and undefined "Phase I trials." Id. at Exs. C and D. In light of the repeated references to clinical studies and studies published in medical journals, the overall impression that the advertisements promote is that this "Phase I trial" is a clinical endeavor. Accordingly, the court finds that the advertisements make the asserted representation.

(C) Spontane-ES claims

The FTC attached a two-page Spontane-ES advertisement to the complaint [Doc. 1, Ex. F]. On the basis of this advertisement, the FTC has asserted that the defendants made the following false and deceptive claims:

Falsity Claim 1: Spontane-ES is clinically proven to be effective in treating 90% of men with erectile dysfunction;

Falsity Claim 2: Spontane-ES is clinically proven to be effective in treating men with erectile dysfunction; and

Falsity Claim 3: Spontane-ES is clinically proven to cause no harmful side-effects.

[Doc. No. 1, ¶¶ 29-30]. In addition, the FTC argues that the defendants made the following LORB claims for Spontane-ES:

LORB Claim 1: Spontane-ES is effective in treating erectile dysfunction in 90% of users; and

LORB Claim 2: Spontane-ES is safe.

Id. at ¶¶ 31-32.

(1) Falsity Claims 1 and 2 and LORB Claim 1

The FTC contends that the Spontane-ES advertisement falsely represents that Spontane-ES is clinically proven to be effective in treating men with erectile dysfunction and that Spontane-ES is clinically proven to be effective in treating 90% of men with erectile dysfunction. The FTC also contends that the advertisement, without a reasonable basis, represents that Spontane-ES is effective in treating erectile dysfunction in 90% of users.

The advertisement clearly represents that Spontane-ES is effective in treating erectile dysfunction. The conspicuous, introductory phrase of the brochure states that Spontane-ES is "THE RIGHT MOVE AGAINST SEXUAL DYSFUNCTION." [Doc. No. 1, Ex. F-1]. On another "Question and Answer" flap of the brochure, the advertisement discusses the causes of erectile dysfunction ("ED"). Id. Two questions later, the advertisement indicates that Spontane-ES will increase libido, "even if you don't have ED." Id. The obvious express and implied meaning of these phrases is that Spontane-ES treats erectile dysfunction, but can be used to enhance the sexual experience "even if you don't have [erectile dysfunction]."

The advertisement also unambiguously states that Spontane-ES has enjoyed a 90 percent success rate among users. [Doc. No. 1, Exs. F-1 and F-2] (stating

that Spontane-ES has had "success rates as high as 90%" and "in preliminary testing, Spontane-ES's active components have been shown to be effective in nearly 90% of all men who have taken it.").[19] Moreover, since the advertisement promotes Spontane-ES as treating erectile dysfunction and enhancing the sexual experience, the obvious, overall implication of the advertisement is that Spontane-ES has a 90% success rate of accomplishing these goals.

Finally, the advertisement also clearly represents that Spontane-ES's success rates were achieved in clinical trials. As noted above, the advertisement states that Spontane-ES has achieved a 90% success rate in "preliminary testing." Id. at F-1. This language follows references to the "research and development" conducted by the "pharmacological staff at Warner Laboratories." Id. Moreover, the testing language is right next to a "Letter from the Doctor," which indicates that Dr. Wright "review[ed]" Spontane-ES. Id. Taken together, the obvious implication from the advertisement is that the success rates were the result of clinical testing.

When the advertisement is read as a whole, it clearly represents that Spontane-ES is clinically proven to be effective in treating men with erectile dysfunction, is clinically proven to be effective in treating 90% of men with erectile dysfunction, and is effective in treating erectile dysfunction in 90% of users. Accordingly, the

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[19] Although one of the references to Spontane-ES's success rates mentions "Spontane-ES's active ingredients," the court concludes that the overall impression conveyed by the advertisement is that Spontane-ES – rather than its individual components – enjoys a 90% success rate.

advertisement makes all three of the claims at issue here.

(2) LORB Claim 2 and Falsity Claim 3

The FTC contends that the Spontane-ES advertisement represents that Spontane-ES is safe and that it is clinically proven to cause no harmful side-effects. In the question and answer segment, the advertisement states:

> Q: Is Spontane-ES safe?
>
> A: Extremely. With five years worth of research and development in each component going into Spontane-ES by the pharmacological staff at WARNER LABORATORIES we have not experienced any harmful side effects to date.

[Doc. No. 1, Ex. F-1] . This segment of the advertisement expressly states that Spontane-ES is safe; therefore, no further analysis of that claim is needed. In addition, this segment of the advertisement also conveys that Spontane-ES has resulted in no harmful side-effects after years of clinical study.[20] Accordingly, the court concludes that the advertisement unambiguously makes both claims as alleged.

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[20] In a column entitled "Final Considerations," the advertisement states,

> CAN I TAKE Spontane-ES WITHOUT RISK TO MY HEALTH? The incidence of side effects is less than 3%!
>
> * The only side effect ever reported is mild nervousness, dizziness, or heart palpitations. If these occur, discontinue use of Spontane-ES.

[Doc. No. 1, Ex. F-2]. By characterizing the side-effects as rare and mild, this statement merely supports the advertisement's overall representation that Spontane-ES has no *harmful* side effects.

ii. Are the Representations Regarding the Products Likely to Mislead?

Having concluded that the advertisements make 22 of the 23 claims targeted by the FTC and that Dr. Wright made 9 of the 10 claims alleged, the court must now determine whether these claims were "likely to mislead" consumers. The court will address the lack of reasonable basis claims before moving on to the falsity claims.

(A) Lack of Reasonable Basis Claims

The FTC has alleged that the lack of reasonable basis claims are likely to mislead consumers because they are unsubstantiated. As indicated above, all of these claims regard the safety and efficacy of dietary supplements; thus, they must be substantiated with competent and reliable scientific evidence. In this case, the FTC has presented expert testimony to establish what constitutes "competent and reliable scientific evidence" for purposes of these claims. The FTC's expert, Dr. Aronne, stated that the type of evidence required to substantiate weight loss claims for any product, including a dietary supplement, is appropriately analyzed results of independent, well-designed, well-conducted, randomized, double-blind, placebo-controlled clinical trials, given at the recommended dosage involving an appropriate sample population in which reliable data on appropriate end points are collected over an appropriate period of time. Dr. Aronne also stated that to scientifically establish the truth of a claim that a product such as Thermalean or Lipodrene has been clinically proven to be efficacious or safe, a reliable clinical study showing that outcome must have been conducted on the product itself. Dr. Aronne further

clarified that anecdotal evidence (i.e., reports from patients) are insufficient to prove the efficacy of a product.

In regard to the Spontane-ES claims, the FTC presented Dr. Melman's expert report. In his report, Dr. Melman states that, to support claims that Spontane-ES is effective in treating erectile dysfunction in 90% of users and is safe, experts in the field of erectile dysfunction would require well-designed, placebo-controlled, randomized, double-blind clinical trials involving an appropriate sample population in which reliable data on the subject's ability to maintain an erection rigid enough and for a sufficient length of time to achieve sexual satisfaction is collected over an appropriate period of time. Dr. Melman stated in his expert report that a study that uses higher doses of the active ingredients or a different combination of active ingredients would not be sufficient to support the efficacy of another product that used lower doses of the active ingredients or a different combination of the ingredients.

The defendants have not countered the testimonies of the FTC's experts regarding what level of substantiation is required for the claims made in this case.[21] Accordingly, the court concludes that there is no issue of fact regarding the requisite levels of substantiation, and will rely upon the standards set forth by Dr. Aronne and Dr. Melman. Both Dr. Melman

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[21] Instead, the defendants have simply argued that the claims were not made and have maintained that the numerous studies regarding the products' ingredients that they relied upon support their ingredient-specific claims. This argument is unavailing because the defendants did, in fact, make the majority of the contested claims.

and Dr. Aronne establish that some form of clinical trial must have been conducted on the product itself or an exact duplicate of the product to substantiate the defendants' claims regarding the overall product. The defendants have admitted that the products themselves have not been clinically or scientifically tested; accordingly, the court finds that the product LORB claims are unsubstantiated and likely to mislead.

(B) Falsity Claims

The FTC has alleged that a number of the defendants' advertising claims are likely to mislead consumers because they are false. The majority of these "falsity claims" assert that a clinical test was performed on the products. All of these claims are inherently false because the defendants have admitted that the products have not been clinically tested.

This leaves only two claims for the court to address on an individual basis. First, the FTC contends that the Thermalean advertisements falsely represent that Thermalean causes rapid and substantial weight loss, including as much as 30 pounds in 2 months. Second, the FTC contends that the Lipodrene advertisements falsely assert that Lipodrene causes substantial weight loss, including as much as 125 pounds.

To demonstrate that both of these claims are false, the FTC cites its expert's testimony that there is no evidence that the active ingredients used in Thermalean and Lipodrene can provide anything more than two pounds per month of weight loss. The defendants dispute this fact; however, rather than specifying the nature of their dispute, they simply point the court to their statement of disputed material

facts numbers 370-420. The court concludes that the defendants' ambiguous reference to 50 statements of fact, without more, is not a proper citation to evidence as required by Local Rule 56.1(B). Even after reviewing these 50 statements of fact, the court can find no concise statement facially countering the FTC's expert testimony. The court is persuaded that the defendants' failure to combat the FTC's expert testimony with anything more than a vague reference to 50 paragraphs is the equivalent of sending the court on a snipe hunt through the defendants' evidence. It is not the role of the court to pinpoint the defendants' evidence for them; accordingly, the court concludes that there is no factual dispute and that the two representations at issue are false and likely to mislead.

iii. Are the Representations Regarding the Products Material?

Having concluded that all of the claims at issue are likely to mislead, the court must determine whether the claims were material to consumer purchasing decisions. As noted at the outset, these health and safety claims are presumed material; however, the defendants may rebut this presumption with extrinsic evidence.

In an effort to do just that, the defendants have presented results from two surveys measuring the impact of the Lipodrene and Thermalean advertisements. These surveys were conducted by the defendants' expert, Dr. Richey. In the first study, Dr. Richey concluded that the advertising as a whole was ineffective in promoting the products and, thus, was not likely a strong driver of consumer intent to purchase the products. In the second survey, Dr. Richey concluded that many claims in the advertisements would not

significantly impact a consumer's decision to purchase a weight loss product.

The court finds that the defendants' evidence is insufficient to create an issue of fact regarding the materiality of the health, safety, and efficacy claims at issue here. First, the FTC has presented evidence that Lipodrene and Thermalean, marketed through the advertisements at issue in this case, generated in excess of $10.6 million in sales between 2001 and 2004. Based on these figures, the court concludes that no reasonable jury could find that the advertisements were ineffective and immaterial to consumers as a whole. Clearly, the advertising appealed to many people and whetted their desire to purchase the Thermalean and Lipodrene products.

Second, the court concludes that Dr. Richey failed to survey the impact of any of the advertising claims at issue in this case, and thus failed to establish that these claims were immaterial. Rather than testing the claims that serve as the basis for the complaint, the study tested small portions of these claims, misstatements of these claims, or claims wholly irrelevant to the case. What survey participants thought of the representations in the survey is irrelevant, as this case concerns only the claims set forth in the complaint. Accordingly, the defendants have failed to present evidence that the claims at issue in this case are immaterial, and the court concludes that there is no basis for this issue to proceed to a trier of fact.

iv. Conclusion Regarding the Product Claims

As described in depth above, the court is satisfied that – with the exception of Thermalean Falsity Claim 1 – the advertisements made all of the asserted claims. The court is likewise satisfied that

Dr. Wright made all of the deceptive endorsement claims except for False Endorsement Claim 1. The court has concluded that all of the claims made were material and likely to mislead. Accordingly, the court holds that the defendants have violated Sections 5 and 12 of the FTC Act.

c. Application of the Law to the Defendants' Medical and Research Facility Claims

In addition to the product claims, the FTC alleges that the defendants' advertising for all three products falsely represented that Warner Laboratories and NICWL are bona-fide research or medical facilities that engage in scientific medical research and product testing at on-site facilities. The FTC argues that the names of the entities alone – "Warner Laboratories" and "National Institute for Clinical Weight Loss" – implies [sic] that they are research or medical facilities. In addition, the FTC argues that the defendants used the following excerpts from the advertisements to advance the perception that NICWL and Warner Laboratories were medical or research establishments:

> At the National Institute for Clinical Weight Loss, Our research and development team has developed a non-prescription formulation that incorporates a naturally occurring equivalent and substitute for Meridia®, Xenical®, and Fastin®. Thermalean™ is the most complete, omni-faceted nutriceutical ever developed for the diet industry!
>
> * * *

> Q. Is Spontane-ES safe? A. Extremely. With five years worth of research and development in each component going into Spontane-ES by the pharmacological staff at WARNER LABORATORIES we have not experienced any harmful side effects to date.
>
> * * *
>
> SYNOPSIS: Upon review of 25,000 women and men participating in the PHASE I Trials, Lipodrene® has been shown to yield an 88% SUCCESS RATE with virtually no side effects.
>
> * * *
>
> On March 1, 1999, the professional staff and Medical Board at WARNER Laboratories aligned with one of the nation's largest manufacturing facilities to begin Phase I testing of Lipodrene, an advanced, pharmaceutical-grade nutriceutical engineered to help women and men lose weight quickly and safely.
>
> * * *
>
> *From the desk of:* Dr. Mark Wright M.D. Chief of Staff, NICWL
>
> * * *
>
> [F]rom Dr. Mark Wright, M.D.-Medical Director for Warner Laboratories

PL's Br., pp. 29-30, attached as Ex. 1 to PL's Mot. for Summ. J. [Doc. No. 172].

The court has reviewed the advertisements, and concludes that they represent that NICWL and Warner Laboratories are entities that engage in scientific medical research and on-site product testing. The court need not

even address whether the companies' names imply that they are medical or science research companies because the language of the advertisements – as highlighted above – clearly represents that these companies engage in the scientific activities alleged.

The FTC argues that the claims are false because neither NICWL nor NUG ever operated a facility that engaged in clinical testing of dietary supplement products. The defendants assert that they did engage in scientific research, and point the court to their statement of material facts nos. 372-422 and 453-461. As noted above, the defendants' citation to more than fifty statements of fact does not constitute an appropriate response. Upon review of these statements, however, the court has determined that they do not represent that NICWL or NUG engaged in on-site research[22] or clinical testing of the weight loss products as the advertisements suggest. Because neither NICWL nor NUG ever performed any clinical tests on the products themselves or conducted any independent research regarding the products, the court concludes that the representations conveyed by the advertisements are false and, therefore, likely to mislead. Moreover, because the representation that NUG and NICWL conducted clinical tests and engaged in scientific research before dispensing the products conveys that the products are safe,

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[22] The statements of fact do represent that NICWL and NUG reviewed the research efforts of independent entities regarding some of the ingredients that were ultimately used in Lipodrene, Thermalean and Spontane-ES. However, this secondary research does not provide support for the advertisements' overall message that NUG and NICWL conducted clinical trials and other types of primary research.

the court concludes that the claims are entitled to the presumption of materiality. The defendants have offered no evidence to rebut this presumption; accordingly, the court concludes that these medical and research facility claims violate the FTC Act.

d. The Defendants' Puffery Defense

As the above analysis indicates, the FTC has demonstrated that the advertisements make false and unsubstantiated claims. Accordingly, the FTC should be entitled to summary judgment. However, the defendants argue that summary judgment is precluded because most of the advertising claims challenged by the FTC constitute non-actionable puffery, and thus, cannot be considered violations of Sections 5 or 12.

Although courts have defined puffery in numerous ways, "'[p]uffing' refers generally to an expression of opinion not made as a representation of fact." FTC v. US Sales Corp., 785 F. Supp. 737, 746 (N.D. Ill. 1992); see also In re Sterling Drug, Inc., 102 F.T.C. 395, 749 (1983) ("Puffing claims are usually either vague or highly subjective and, therefore, incapable of being substantiated."). While the law affords a seller "some latitude in puffing his goods . . . he is not authorized to misrepresent them or to assign to them benefits they do not possess. Statements made for the purpose of deceiving prospective purchasers cannot properly be characterized as mere puffing." US Sales Corp., 785 F. Supp. at 746; see also United States v. Simon, 839 F.2d 1461, 1468 (11th Cir. 1988) (citing United States v. New South Farm & Home, 241 U.S. 64 (1916)) ("[W]hen a proposed seller goes beyond [exaggerating the qualities which the article has and] assigns to the article qualities it does not possess, [when the seller] does not simply magnify in opinion the advantages [but] falsely asserts their

existence, he transcends the limits of 'puffing' and engages in false representations and pretenses."). Thus, the Eleventh Circuit has concluded that when an advertiser places "otherwise general assertions about the value [of a product] into a concrete factual setting," the advertiser creates representations that are either true or false, not mere puffery. Simon, 839 F.2d at 1468.

The advertisements at issue in this case are indisputably riddled with puffery and, thus, create many overall impressions that could not serve as the basis for Section 5 or Section 12 violations. To demonstrate the rampant use of puffery, the defendants go through the advertisements sentence by sentence and sometimes even phrase by phrase to point out any language that could fit – even in the remotest sense – within the definition of puffery. By deconstructing the advertisements, the defendants attempt to create the overall impression that substantive claims could not arise from such vague, subjective statements.

Despite the defendants' focus on the words and phrases of the advertisements, the focus of this case is on the claims derived from each of the advertisements as a whole. All of the claims that the FTC articulates in the complaint are phrased as factual statements that can be verified by research and science. As discussed in-depth above, the court has reviewed the advertisements, and has concluded that they clearly and conspicuously make the majority of these claims. To be sure, some of the advertisements' direct language supporting these claims contains puffery; however, the combination of this puffery with the concrete, factual statements and phrases that also comprise the advertisements results in the claims highlighted in the

complaint. The fact that puffery is present cannot serve as a shield for the advertisements' deceptive, factual representations. Accordingly, the court concludes that puffery is not a justifiable defense, and the FTC is entitled to summary judgment.

e. The Defendants' Liability

In this case, the FTC seeks to hold all of the defendants liable for the deceptive advertising of Thermalean, Lipodrene, and Spontane-ES. In addition, the FTC seeks to hold Dr. Wright liable for his deceptive endorsements. The parties' respective liability is analyzed below.

i. NUG, NICWL, and Hi-Tech's Liability

As noted in the discussion of Hi-Tech's motion for summary judgment, NUG, NICWL, and Hi-Tech operated as a common enterprise and thus are jointly liable for any deceptive advertising attributable to any of them individually. Since the defendants do not dispute that NUG disseminated the Lipodrene and Spontane-ES advertisements and that NICWL disseminated the Thermalean advertisements, each of the corporate defendants are jointly liable for the FTC Act violations contained in these deceptive advertisements.

ii. Liability of Defendants Wheat. Smith, and Holda

In a case brought by the FTC, individual defendants:

> are liable for the corporate defendant's violations if the FTC demonstrates that (1) the corporate defendant violated the FTC Act; (2) the individual defendants participated directly in the

> wrongful acts or practices or the individual defendants had authority to control the corporate defendants; and (3) the individual defendants had some knowledge of the wrongful acts or practices.

Windward Marketing, 1997 U.S. Dist. LEXIS 17114, at *38; see also FTC v. Gem Merchandising Corp., 87 F.3d 466, 470 (11th Cir. 1996) ("[T]he FTC must show that the individual defendants participated directly in the practices or acts or had authority to control them. . . . The FTC must then demonstrate that the individual had some knowledge of the practices."). If a defendant was a corporate officer of a small, closely-held corporation, that individual's status gives rise to a presumption of ability to control the corporation. FTC v. Transnet Wireless Corp., 506 F. Supp. 2d 1247, 1270 (S.D. Fla. 2007). To establish the knowledge requirement, the FTC need not demonstrate actual knowledge of material misrepresentations; instead, the FTC may meet this element by "showing that [an] individual had 'actual knowledge of material misrepresentations, reckless indifference to the truth or falsity of such misrepresentations, or an awareness of a high probability of fraud along with an intentional avoidance of truth.'" Transnet, 506 F. Supp. 2d at 1270 (citing FTC v. Army Travel Services, Inc., 875 F.2d 564, 574 (7th Cir. 1989). "A defendant's participation in corporate affairs is probative of knowledge." FTC v. Wilcox, 926 F. Supp. 1091, 1104 (S.D. Fla. 1995).

In this case, Wheat, Holda, and Smith were all corporate officers, owners, and/or independent contractors or employees of NUG, NICWL, and Hi-Tech.

In these roles, these individuals clearly had the ability to control the corporate defendants. Many of the examples in the record of Wheat, Holda, and Smith's involvement with the companies indicate that they knew of, or at least were recklessly indifferent to, the misrepresentations the advertisements made.[23] Rather than repeating each of those instances here, the court finds it sufficient to note that the defendants, in their motion for summary judgment, do not even dispute the individual defendants' knowledge of the advertisements' misrepresentations. Accordingly, this court finds that the individual defendants are liable for the violations of the FTC Act promulgated by the corporate defendants.

iii. Dr. Wright's Liability

The FTC petitions this court to hold Dr. Wright individually liable for his participation in marketing Thermalean. Here, the record is clear that Dr. Wright participated directly in the advertising and knew that the advertisements made material misrepresentations regarding the product claims or at least was recklessly indifferent to the truth or falsity of the advertisements. Dr. Wright helped develop the products, reviewed the substantiation regarding the ingredients in the products, and reviewed and edited the advertisements before they were disseminated. He allowed himself to be called "Chief of Staff" and "Medical Director" in the advertisements. He knew that no clinical trials had ever been conducted on the products and conducted no such trials himself. He was aware that

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[23] Significantly, each of the individual defendants testified that he had a hand in creating the advertisements or reviewing them prior to dissemination.

none of the studies that he reviewed were conducted on any of the products sold by the defendants. Most importantly, Dr. Wright does not contest his individual liability for the corporate defendants' wrongs; instead, he simply joins the corporate defendants in arguing that no violations occurred. As discussed above, the corporate defendants did engage in violations of the FTC Act; accordingly, Dr. Wright is individually liable for his participation in those violations.

The FTC also seeks to hold Dr. Wright liable for his deceptive endorsements of Thermalean. The FTC guidelines state that an expert's endorsement:

> must be supported by an actual exercise of his expertise in evaluating product features or characteristics with respect to which he is expert and which are both relevant to an ordinary consumer's use of or experience with the product and also are available to the ordinary consumer. This evaluation must have included an examination or testing of the product at least as extensive as someone with the same degree of expertise would normally need to conduct in order to support the conclusions presented in the endorsement.

Guides Concerning Use of Endorsements and Testimonials in Advertising, 16 CFR § 255.3 (2008). The FTC has presented evidence that a physician would require scientific evidence regarding the product itself (rather than its individual components) before making many of the claims that Dr. Wright made, and Dr. Wright has not contested this evidence. Dr. Wright has admitted that he did not rely on any scientific studies

regarding the Thermalean product when making his endorsement; thus, Dr. Wright did not examine or test the product at least as extensively as someone with the same degree of expertise would normally need to examine or test the product before making the conclusions he presented in the endorsement.

Because Dr. Wright did not base his endorsements on the substantiation that a similarly positioned expert in his field would require when making such endorsements, his endorsements were deceptive. Accordingly, the court holds that Dr. Wright is liable for making deceptive endorsements that violate the FTC Act.

f. Relief Requested by the FTC

In its motion for summary judgment, the FTC has requested an award of permanent injunctive relief, as outlined in its proposed order, from ongoing violations by the corporate defendants and defendants Wheat, Smith, and Holda. Moreover, the FTC has requested that the court award equitable monetary relief against the corporate defendants and defendants Wheat, Smith, and Holda, and has further requested that the court hold these parties jointly and severally liable. The FTC has also requested that the court award injunctive and equitable relief against Dr. Wright, as outlined in a proposed final judgment drafted specifically in regard to this defendant.

The defendants contest the FTC's entitlement to the relief requested, and argue that an award of joint and several liability would be unjust. The court will address the defendants' concerns and liability below.

i. The FTC's Entitlement to Permanent Injunctive Relief from the Corporate Defendants and Wheat. Holda, and Smith[24]

Under Section 13(b) of the FTC Act, the FTC may seek, and the court may grant, a permanent injunction to prevent future violations of "any provisions of law enforced by the FTC." 15 U.S.C. § 53(b); FTC v. Evans Products Co., 775 F.2d 1084, 1086 (9th Cir. 1985). As this court concluded in its June 24, 2005, order, the FTC must have reason to believe that the violation is ongoing or likely to recur as a prerequisite to seeking a permanent injunction. Order, June 24, 2005, p. 11 [Doc. No. 75].

Although this court may not grant injunctive relief in favor of the FTC if there is no likelihood that the defendants' violations will recur, "the fact that illegal conduct has ceased does not foreclose injunctive relief." FTC v. Citigroup Inc., 239 F. Supp. 2d 1302, 1306 (N.D. Ga. 2001). If the FTC is able to demonstrate that there is "some cognizable danger of recurrent violation, something more than a mere possibility," then the FTC is entitled to injunctive relief. United States v. W.T. Grant Co., 345 U.S. 629, 633 (1953); United States v. Realty Multi-List, Inc., 629 F.2d 1351, 1388 (5th Cir. 1980) (applying standard for injunction in this circuit). In determining whether there is a "cognizable danger of future violations," this

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[24] The defendants have requested that the court consider here the arguments articulated in their motion for summary judgment on this issue. Accordingly, the court will consider both the defendants' and the FTC's briefing on this issue as found in the documents associated with the defendants' motion for summary judgment.

court has previously looked to the nature of the alleged violations, whether the defendants' current occupations position them to commit future violations, and the alleged harm to consumers if the wrongs recur. Citigroup, 239 F. Supp. 2d at 1306.

The court concludes that the FTC is entitled to a permanent injunction impacting NUG, Hi-Tech, Wheat, Holda, and Smith.[25] The evidence clearly demonstrates that the corporate defendants' previous violations of the FTC Act were numerous and grave. These parties, acting through their corporate officers, did not engage in a harmless advertising scheme with an isolated incidence of deception; instead, their advertising was chock-full of false, misleading, and unsubstantiated information. This deceptive propaganda was not simply distributed through magazine advertisements and other general circulation media that could easily be "tuned-out" by consumers; rather, it was also sent directly to pre-determined lists of individuals who were especially vulnerable to such targeted advertisement. In short, the defendants dispensed deception to those with the greatest need to believe it, and – not surprisingly – generated a handsome profit for their efforts.

In addition to the gravity of the past violations, the court concludes that the need for a permanent injunction is supported by the evidence on the record of

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[25] The defendants have argued that the FTC is not entitled to injunctive relief against NICWL because NICWL is dissolved. The court is persuaded by the defendants' arguments, and concludes that it is unnecessary to enter a permanent injunction against a corporation that is no longer in existence. Accordingly, the court DENIES the FTC's request for injunctive relief from NICWL.

NUG and Hi-Tech's current activities. Although they contend that they no longer advertise or even make the exact formulations of the products at issue, both NUG and HiTech continue to market – through direct mail – dietary supplements similar to the dietary supplements that are discussed in this lawsuit. Significantly, Hi-Tech continues to market a product called Lipodrene, and callously continues to use – almost verbatim – NICWL's old Thermalean brochure to market this product. Thus, it is readily apparent that NUG and Hi-Tech's current business endeavors could serve as a platform for continuing violations of the FTC Act.

If NUG and Hi-Tech's violations recur, the harm to consumers is certain and serious. The advertisements that they disseminated deceived consumers into spending approximately $15.8 million; accordingly, future violations of a similar nature will almost certainly result in financial harm to consumers. More concerning, however, is the physical harm that these types of deceptive claims could foreseeably inflict on consumers' health. It is easy to imagine that a consumer, relying upon false and unsubstantiated advertising about a dietary supplement's safety, efficacy, and ability to conquer health threatening circumstances, could forgo a much needed medical appointment. Moreover, it is also easy to imagine the physical harm that a consumer, relying upon a product's assertions of safety and clinical testing, might experience when suddenly struck by a violent side effect. These are but two examples of many that this discussion could generate. Thus, it is clear to the court that the recurrence of the corporate defendants' violations could cause significant harm to consumers.

Although a permanent injunction is clearly proper under these circumstances, the defendants make one last argument against it. They claim that the Consent Decree they entered into with the FDA requires them to submit all advertising efforts to the FDA prior to dissemination and, thus, makes it extremely unlikely that they will violate the FTC Act. Because the FDA applies "a standard that is 'consistent with' the FTC's approach" when reviewing advertisements, the defendants argue that "any oversight remedy sought by the FTC in this case" is redundant and not in the public interest. [Doc. No. 168, p. 48].

Upon review of the admissible evidence, the court concludes that the defendants' arguments are groundless. First, the Consent Decree only applies to the FDA defendants; thus, it has no impact on the behavior of Holda, Smith, or Wright. Second, none of the terms of the Consent Decree appear to require the FDA to pre-screen every advertisement issued by the FDA defendants,[26] rendering the defendants' arguments that

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[26] The Consent Decree, entered into in 2003, required the FDA defendants to retain an independent auditor to conduct inspection of the defendants' advertising and labeling to ensure that they were no longer making drug claims and that they were appropriately tracking and investigating adverse events. There is no evidence that this auditor was ensuring that the defendants were not disseminating misbranded dietary supplements or engaging in other FTC Act violations. However, even if this auditor did keep a watchful eye for these violations, there is no evidence that the auditor was required to continue to pre-screen the defendants' products after they were introduced or re-introduced into the market. The Consent Decree did require the FDA defendants to retain an auditor to conduct inspections of their operations at least twice a year for two years after they resumed operations to ensure compliance with the Food, Drug and Cosmetic Act ("FDCA"). Consent Decree, ¶ 11 [Doc. No. 168, Ex. I]. If still ongoing, these

they are prevented from dispensing deceptive advertising unsubstantiated. Finally, the injunctive relief sought in this case is not identical to the relief achieved by the FDA Consent Decree and, thus, does not present any public interest concerns. The focus of the FDA Consent Decree is unauthorized drug claims, not false or misleading claims regarding dietary supplements. Although the FDA and FTC may attempt to apply consistent standards when evaluating advertisements, nothing in the Consent Decree indicates that the FDA was actively evaluating the defendants' advertisements for all of the issues present here.

Even if there is some overlap between the Consent Decree and the injunctive relief requested here, it does not follow that the injunctive relief is not in the public interest. Generally, any action commenced by the FTC to "stop deception in its incipiency" will be deemed in the public interest. Reaina Corp. v. Federal Trade Commission, 322 F.2d 765, 768 (3d Cir. 1963) (citing Progress Tailoring Co. v. Federal Trade Commission, 153 F.2d 103, 105 (7th Cir. 1946). This action seeks to prevent the defendants from continuing to violate the FTC Act by: (1) enjoining the defendants from continuing violations, and (2) requiring the defendants to bear the consequences of their previous violations by compensating consumers for money spent on the defendants' deceptively advertised products. Although the public interest is not necessarily served when one

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bi-annual visits hardly constitute an injunctive prohibition against disseminating deceptive advertising; rather, they seem to function more as a check-in to ensure the defendants have not violated the Consent Decree. Moreover, the defendants have pointed the court towards no evidence establishing that these audits are still ongoing.

agency duplicates the gains that another agency has already achieved, see June 24, 2005, Order, p. 49 [Doc. No. 75], an action like this which seeks new, more targeted relief is not against the public interest simply because the injunctive relief requested inadvertently echoes the injunctive relief already achieved in some respects.[27]

As indicated above, there is ample reason for the FTC to believe that the violations are likely to recur. Accordingly, the FTC is entitled to injunctive relief from NUG and Hi-Tech. As Wheat, Holda, and Smith have admitted continuing involvement in these corporations, the FTC is entitled to injunctive relief from these individual defendants as well.

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[27] Practically speaking, the court notes that the defendants' real motivation in making their public interest argument appears to be avoiding monetary liability, not injunctive relief. If the Consent Decree really does, as the defendants argue, prohibit and reign in all of the activities that the FTC seeks to enjoin in this case, the defendants would have no reason to contest the injunctive relief here because it creates no new restraints for them. However, the defendants argue that all monetary relief requested is contingent upon the grant of a permanent injunction; therefore, they claim that if the court does not grant a permanent injunction, it cannot award monetary redress. This contention is not correct. Even if the primary injunctive relief is not requested, the court is still entitled to grant other equitable remedies. See FTC v. Southwest Sunsites, Inc., 665 F.2d 711, 717-18 (5th Cir. 1982) ("[It is] indisputably clear that a grant of jurisdiction such as that contained in Section 13(b) carries with it the authorization for the district court to exercise the full range of equitable remedies traditionally available to it.") (internal citations omitted); In re Evans Products Co., 60 B.R. 863, 867 (S.D. Fla. 1986) ("The district court's power under § 13(b) to exercise the full range of equitable remedies, including rescission and restitution, is not diminished by the fact that primary injunctive relief might not be granted.").

ii. The FTC's Entitlement to Monetary Relief from the Corporate Defendants and Wheat, Holda, and Smith

In addition to injunctive relief, the FTC has requested monetary relief from the corporate defendants and Wheat, Holda, and Smith. "A corporation is liable for monetary relief under Section 13(b) if [the FTC] shows that the corporation engaged in misrepresentations or omissions of a kind usually relied on by reasonably prudent persons and that consumer injury resulted." Natural Solutions, Inc., 2007 U.S. Dist. LEXIS 60783, at *19. "To demonstrate reliance and resulting consumer injury, [the FTC] must prove that [the] 'defendant made material representations, that they were widely disseminated, and that consumers purchased the defendant's product.'" Id. (citing FTC v. Figgie International, Inc., 994 F.2d 595, 606 (9th Cir. 1993)).

As established in detail above, the advertisements made many material misrepresentations. Moreover, the FTC has conclusively demonstrated that the advertisements were widely disseminated. [28] Finally, the FTC has

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[28] The FTC has established that approximately 10 million copies of the Thermalean advertisements attached to the complaint were mailed to consumers between the first half of 2001 and the first half of 2003. Defs.' Resp. to FTC's Statement of Facts, ¶¶ 114 and 130 [Doc. No. 197]. Similarly, the FTC has demonstrated that approximately 4 million copies of the Lipodrene advertisement attached to the complaint as Exhibit D were mailed to consumers, that the Lipodrene advertisement attached to the complaint as Exhibit C was placed in Cosmopolitan Magazine, and that the Lipodrene advertisement attached to the complaint as Exhibit E was maintained on an internet website. Id. at ¶¶ 67, 166, and 188. The FTC has also demonstrated that approximately 4 million copies of the

proven that consumers spent $7,456,010.00 on Thermalean between May 1, 2001, through March 31, 2004; that consumers spent $3,163,073.00 on Lipodrene between January 1, 2001, and March 31, 2004; and that consumers spent approximately $5,263,353.00 on Spontane-ES between January 1, 2001, and March 31, 2004. Defs.' Resp. to FTC's Statement of Facts, SISI 248, 250, and 313 [Doc. No. 197]. Thus, it is clear that consumers purchased the products at issue. Accordingly, the defendants are liable for consumer redress.

In similar Section 13(b) actions, "the proper amount of restitution has been held to be the purchase price of the relevant product or business opportunity, less any refunds." US Sales Corp., 785 F. Supp. at 753; Transnet Wireless Corp., 506 F. Supp. 2d at 1271; Peoples Credit First, 2005 U.S. Dist. LEXIS 38545, at *29, n.18. The primary purpose of restitution in the context of deceptive advertising is to restore victims to their position prior to the deceptive sales. Thus, in calculating a refund, the court looks to the price paid by the consumer and does not deduct any value received. Figgie International, 994 F.2d at 606.

Using the above formula, the FTC claims that the defendants are jointly and severally liable for $15,882,436.00.[29] The defendants argue that this figure

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Spontane-ES advertisement in Exhibit F of the complaint were mailed to consumers. Id. at ¶ 260.

[29] This figure represents the total of $7,456,010.00 in Thermalean sales between May 1, 2001, and March 31, 2004; $3,163,073.00 in Lipodrene sales between January 1, 2001, and March 31, 2004; and $5,263,353.00 in Spontane-ES sales between January 1, 2001, and March 31, 2004.

is improper because it represents the amount of the sales to consumers rather than profits made by the defendants. In addition, the defendants argue that the damages should be reduced by the amount of sales to customers who reordered the product. The defendants further argue that this figure presumes joint and several liability, which they contend is improper in this case. Finally, the defendants request that the court allow them to pay consumer redress directly to their customers rather than to the FTC.

The defendants have provided no case law in support of their position that consumer redress should be measured by the profits made by the defendants rather than the expenses incurred by consumers, and the court concludes that this argument does not comport with the theory behind restitution. Restitution is intended to return the injured party to the status quo and is measured by the amount of loss suffered by the victim. Transnet Wireless Corp.. 506 F. Supp. 2d at 1271. Requiring the defendants to return the profits that they received rather than the costs incurred by the injured consumer would be the equivalent of making the consumer bear the defendants' expenses. The court will not make the victimized consumers shoulder such a burden.

The court finds the defendants' second argument – that the damages should be reduced by the amount of sales to customers who reordered the product – equally unavailing. Essentially, the defendants argue that they should not be required to compensate customers who reordered the products because "those customers were obviously influenced by their actual experience with the product and not the advertisement." [Doc. No. 196, p. 58]. The defendants do

not introduce any evidence of what actually influenced the customers' decisions to reorder the products; instead, they merely speculate that it was the customers' experiences rather than the advertisements.

While it may be logical to infer that the customers who reordered the defendants' products relied to some degree upon their experience with the products, the fact that the customers' experiences played a role in their purchasing decisions does not mean or even imply that the customers did not also rely upon the representations in the advertisements when making their subsequent purchases.[30] The FTC has demonstrated that the defendants made material representations, that the misrepresentations were widely disseminated, and that consumers purchased the defendants' products; thus, the court may presume that the consumers actually relied upon the advertisements, even when making subsequent purchases. See Figgie International. 994 F.2d at 605-06. To rebut this presumption, the defendants must introduce evidence demonstrating that the repeat customers did

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[30] Indeed, the advertisements contain several express statements that indicate that consumers who reorder the products and use them long term will see favorable results. See Doc. No. 1, Ex. A-4 (noting that Thermalean recipients can expect to lose a whopping 73 pounds in a year); Id. at Ex. A-6 ("Thermalean users can expect to lose 30 pounds in 60 days"); Id. at Ex. C (noting that Lipodrene can help customers achieve their weight loss goal of 125 pounds and can also help customers lose up to 42% of their total body fat). In addition, the Spontane-ES advertisement indicates that the product is in short supply and encourages customers to purchase it quickly before it is no longer available [Id. at Ex. F-1]. This type of advertisement could have encouraged multiple orders and rapid re-orders from customers who were particularly vulnerable to the extreme promises made by the advertisement.

not rely on the advertisements. Id. at 606. The defendants have presented nothing more than mere speculation in this regard and, thus, have failed to meet their burden. Accordingly, the court will not reduce the defendants' monetary liability by the amount of the sales to consumers who reordered the products.

Next, the defendants argue that they should not be held jointly and severally liable because the advertisements were promulgated by different companies, albeit companies with overlapping but not identical ownership. In short, the defendants seem to argue that they are not all liable for the same violations and, thus, should not be held jointly and severally liable as if they were.

The FTC has demonstrated that the corporate defendants acted as a common enterprise. Consequently, each corporation may be held liable for the actions of the other corporations. Because all of the individual defendants are liable for the corporations' actions, joint and several liability is appropriate here.

Finally, the defendants request that the court allow them to pay consumer redress directly to the purchasers of its products rather than to the FTC. The defendants propose contacting every single customer and providing or offering to provide each customer with a complete refund. The FTC, on the other hand, has proposed that all funds earmarked for consumer redress be deposited into a fund in its name to be used for consumer redress and any attendant expenses for the administration of such equitable relief. If the FTC determines that consumer redress is wholly or partially impracticable or if funds remain after redress is completed, the FTC has proposed using any remaining funds for such other equitable relief as it determines to be

related to the defendants' practices as alleged in the complaint. The FTC proposes depositing any additional funds into the United States Treasury as disgorgement.

The court has ample discretion to grant the FTC's requested relief, and the defendants have offered no compelling reason why they, the purveyors of the deception, should be charged with competently and honestly reimbursing the consumers. Hence, the court denies the defendants' request.

The FTC has demonstrated that it is entitled to the consumer redress requested. Accordingly, the court finds NUG, NICWL, HiTech, Wheat, Holda, and Smith jointly and severally liable for $15,882,436.00.

iii. Remedy Against Dr. Wright

The FTC has requested that this court enter a permanent injunction against Dr. Wright. The FTC has also requested that the court order disgorgement of ill-gotten gains from Dr. Wright in the amount of $15,454.00 for his participation in the deceptive marketing of the products.

Dr. Wright contends that the FTC is not entitled to injunctive relief from him because the FTC can show no "cognizable danger" that he will violate the law again. Dr. Wright contends that, if the FTC is not entitled to a permanent injunction, it is barred from recovering any ancillary damages from him.

Dr. Wright's arguments are unpersuasive. As detailed above, Dr. Wright's previous violations of the FTC Act were significant. In the Thermalean advertisement alone, he made numerous false and unsustainable endorsements that afforded the product an air of clinical safety that it otherwise may not have

had.[31] Moreover, the FTC has demonstrated that Dr. Wright is still making endorsements for the defendants. Indeed, in a recent Lipodrene brochure, Dr. Wright makes some of the very same claims at issue in this case. While the FTC has not attacked the new Lipodrene brochure in this action, Dr. Wright's continuing endorsements indicate, at the very least, that he is positioned to commit future violations of the FTC Act. Finally, any future FTC Act violations on the part of Dr. Wright will likely result in monetary and physical harm similar to that discussed in regard to future violations on the part of the corporate defendants. Thus, it is clear that injunctive relief is warranted against Dr. Wright.

Other than arguing that the FTC is not entitled to a permanent injunction against him, Dr. Wright does not contest the monetary damages that the FTC seeks. Accordingly, the court finds that the FTC is entitled to the monetary relief requested.

iv. Entry of the Proposed Orders

The FTC has provided the court with two proposed orders in this case. In these proposed orders, the FTC sets forth the injunctive relief that it seeks from the defendants, the monetary relief requested, and monitoring and other provisions.

The defendants have requested that the court grant them further opportunity to address issues raised by the proposed orders before the court adopts them. Citing "space limitations," they contend that they were unable to fully address the "numerous deficiencies" in

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[31] Although the FTC only pursues this action against Dr. Wright for his involvement in the Thermalean advertising campaign, his participation in the deceptive Lipodrene and Spontane-ES advertisements is obvious.

the proposed orders. Defs.' Resp. Br., p. 58 [Doc. No. 196].

In the interest of justice, the court will grant the defendants' request. However, the court cautions the defendants that it is persuaded by case law that "injunctive relief may be broader than the violations alleged in the complaint as long as the relief is reasonably related to the violations of the FTC Act which occurred, and is not too indefinite." United States v. Vend Direct, Inc., C.A. No. 06-cv-02423, 2007 U.S. Dist. LEXIS 83759, at *6 (D. Colo., July 26, 2007); see also SlimAmerica, 77 F. Supp. 2d at 1275 ("Broad injunctive provisions are often necessary to prevent transgressors from violating the law in a new guise."). Thus, the defendants are instructed to concisely frame their objections with this standard in mind.

IV. Conclusion

Pursuant to the reasons stated herein, the court **DENIES** the defendants' motion to strike the declaration of Jennifer Thomas [Doc. No. 214], **DENIES** Hi-Tech's motion for summary judgment [Doc. No. 170], and **DENIES** the defendants' motion for summary judgment [Doc. No. 168]. The court **GRANTS** the FTC's motion for summary judgment [Doc. No. 172]. The court concludes that the FTC is entitled to a permanent injunction against all parties, with the exception of NICWL. In addition, the court concludes that defendants NUG, NICWL, Hi-Tech, Wheat, Holda, and Smith are jointly and severally liable for $15,882,436.00 in consumer redress, and that Dr. Wright is liable for $15,454.00.

The defendants are hereby **ORDERED** to submit to the court, within 15 days, any objections they have to the proposed orders presented by the

FTC. The FTC will then have 15 days to file any response to the defendants' objections. Both parties are **INSTRUCTED** to limit their response to **ten (10) pages.** In addition, both parties are **INSTRUCTED** to include any citations to the record in their briefs, and are further **INSTRUCTED** to cite directly to any supporting evidence that they wish the court to consider.

SO ORDERED, this 4th day of June, 2008.

CHARLES A. PANNELL, JR.
United States District Judge

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 09-10617

Federal Trade Commission,
Plaintiff-Counter-Defendant-
Appellee,

v.

National Urological Group, Inc.,
d.b.a. Warner Laboratories,
Defendant-Counter-Claimant-
Appellant,
National Institute for Clinical
Weight Loss, Inc.
Defendant-Counter-Claimant,
Hi-Tech Pharmaceuticals, Inc.,
Corporations, Jared Wheat, Thomasz
Holda, individually and as officers of
the corporations, Stephen Smith,
individually and as officer of National
Urological Group, Inc., and National
Institute for Clinical Weight Loss,
Inc., Terrill Mark Wright, M.D.,
individually,
Defendants-Appellants.

Appeal from the United States District Court
for the Northern District of Georgia

Filed U.S. Court of Appeals, Eleventh Circuit
April 26, 2010, John Ley, Clerk

ON PETITION FOR REHEARING AND
PETITION FOR REHEARING EN BANC

Before: DUBINA, Chief Judge, BIRCH and BLACK, Circuit Judges.

PER CURIAM:

The Petition for Rehearing is DENIED and no Judge in regular active service on the Court having requested that the Court be polled on rehearing en banc (Rule 35, Federal Rules of Appellate Procedure), the Petition for Rehearing En Banc is DENIED.

ENTERED FOR THE COURT: April 26, 2010

Constitutional and Statutory Provisions

I. U.S. Const., Amend. 1: Congress shall make no law . . . abridging the freedom of speech . . . .

II. The FTC Act

15 U.S.C. § 45 provides in relevant part:

§ 45. Unfair methods of competition unlawful; prevention by Commission

(a) Declaration of unlawfulness; power to prohibit unfair practices; inapplicability to foreign trade

(1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.

(2) The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations, except banks, savings and loan institutions described in section 57a(f)(3) of this title, Federal credit unions described in section 57a(f)(4) of this title, common carriers subject to the Acts to regulate commerce, air carriers and foreign air carriers subject to part A of subtitle VII of Title 49, and persons, partnerships, or corporations insofar as they are subject to the Packers and Stockyards Act, 1921, as amended, except as provided in section 406(b) of said Act, from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.

15 U.S.C. § 52 provides:

§ 52. Dissemination of false advertisements

(a) Unlawfulness

It shall be unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement--

(1) By United States mails, or in or having an effect upon commerce, by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of food, drugs, devices, services, or cosmetics; or

(2) By any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce, of food, drugs, devices, services, or cosmetics.

(b) Unfair or deceptive act or practice

The dissemination or the causing to be disseminated of any false advertisement within the provisions of subsection (a) of this section shall be an unfair or deceptive act or practice in or affecting commerce within the meaning of section 45 of this title.

III. DSHEA

21 U.S.C. § 321 provides in relevant part:

§ 321. Definitions; generally

For the purposes of this chapter--

* * * *

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

* * * *

(ff) The term "dietary supplement"--

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
(A) a vitamin;
(B) a mineral;
(C) an herb or other botanical;
(D) an amino acid;

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) means a product that--

(A)(i) is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this title; or

(ii) complies with section 350(c)(1)(B)(ii) of this title;

(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(C) is labeled as a dietary supplement;

* * * *

Except for purposes of paragraph (g) and section 350f of this title, a dietary supplement shall be deemed to be a food within the meaning of this chapter.

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(2)

Supreme Court, U.S.
FILED
SEP 24 2010

No. 10-125

In the Supreme Court of the United States

NATIONAL UROLOGICAL GROUP, INC., ET AL.,
PETITIONERS

v.

FEDERAL TRADE COMMISSION

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the judgment below, which imposed liability on petitioners under the Federal Trade Commission Act for disseminating advertisements that the district court determined to be false and misleading, violated petitioners' First Amendment right to engage in commercial speech.

2. Whether the Federal Trade Commission's standard for determining whether a dietary supplement advertisement has sufficient substantiation is unconstitutionally vague.

3. Whether the judgment below conflicts with the Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325.

4. Whether the district court correctly determined that there were no disputed issues of material fact.

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In the Supreme Court of the United States

No. 10-125

NATIONAL UROLOGICAL GROUP, INC., ET AL.,
PETITIONERS

v.

FEDERAL TRADE COMMISSION

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-2a) is not published in the *Federal Reporter* but is reprinted in 356 Fed. Appx. 358. The opinion of the district court (Pet. App. 3a-86a) is reported at 645 F. Supp. 2d 1167.

JURISDICTION

The judgment of the court of appeals was entered on December 15, 2009. A petition for rehearing was denied on April 26, 2010 (Pet. App. 87a-88a). The petition for a writ of certiorari was filed on July 23, 2010. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Petitioners are two closely held companies (National Urological Group, Inc. and Hi-Tech Pharmaceuticals, Inc.), officers of those companies (Jared Wheat, Thomasz Holda, and Stephen Smith), and a medical doctor affiliated with them (Terrill Mark Wright). Pet. App. 4a. Along with a now-dissolved company, petitioners have collectively been responsible for the production, marketing, and sale of the weight-loss supplements Thermalene and Lipodrene, and the erectile-performance supplement Spontane-ES. *Id.* at 4a & n.1, 79a.

Petitioners produced advertisements for these supplements that touted their efficacy and safety, frequently by reference to scientific and clinical studies. Pet. App. 34a-56a. The advertisements claimed, for example, that "Thermalean's scientifically proven formula" had yielded a "42% reduction in body fat" in "independent university-sponsored trials"; that Lipodrene is "[c]linically PROVEN to be SAFE AND EFFECTIVE"; and that "in preliminary testing, Spontane-ES's active components have been shown to be effective in nearly 90% of all men who have taken it." *Id.* at 44a, 53a, 55a (citations omitted). The advertisements also indicated that petitioners themselves were actively engaged in product testing. See, *e.g.*, *id.* at 63a (quoting advertisement's claim that one of the corporate petitioner's "professional staff and Medical Board" had "aligned with one of the nation's largest manufacturing facilities to begin Phase I testing of Lipodrene").

In fact, however, petitioners had never conducted, nor were they aware of, any clinical or scientific studies conducted on any of these supplements. Pet. App. 59a. Petitioners instead relied solely on studies that had

tested individual ingredients of their products, but without testing the efficacy or safety of those ingredients in the particular dosages and combinations that petitioners were marketing. *Id.* at 58a & n.21. Petitioners themselves, moreover, maintained no medical or scientific facilities for product testing. *Id.* at 64a.

2. a. Respondent Federal Trade Commission (FTC or Commission) is "empowered and directed" by the Federal Trade Commission Act "to prevent * * * unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C. 45(a)(2). The statutory definition of "unfair or deceptive act or practice" includes the dissemination of "any false advertisement * * * for the purpose of inducing, or which is likely to induce, * * * the purchase in or having an effect upon commerce, of food, drugs, devices, services, or cosmetics." 15 U.S.C. 52. The Commission can establish a violation of these provisions by showing that a defendant has made a material representation that is likely to mislead reasonable consumers. See, *e.g.*, *FTC* v. *Cyberspace.com LLC*, 453 F.3d 1196, 1199 (9th Cir. 2006); *FTC* v. *Bay Area Bus. Council, Inc.*, 423 F.3d 627, 635 (7th Cir. 2005); *FTC* v. *Tashman*, 318 F.3d 1273, 1277 (11th Cir. 2003).

Under the FTC's longstanding interpretation of the Act, as set forth in its policy statements and adjudicatory decisions, an advertisement is misleading not only if it makes claims that are provably untrue, but also if it makes claims that the advertiser "lack[s] a reasonable basis" to support. Pet. App. 4a; see, *e.g.*, *FTC* v. *Pantron I Corp.*, 33 F.3d 1088, 1096 n.22 (9th Cir. 1994), cert. denied, 514 U.S. 1083 (1995); *Thompson Med. Co., Inc.* v. *FTC*, 791 F.2d 189, 193 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987); *FTC Policy Statement on Deception* n.5 (Oct. 14, 1983), http://www.ftc.gov/

bcp/policystmt/ad-decept.htm. With respect to health-related claims, the Commission has required that an advertising claim be supported by "competent and reliable scientific evidence." FTC, *Dietary Supplements: An Advertising Guide for Industry* 9 (2001), http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.pdf (*Dietary Supplements Guide*); see, *e.g.*, *Removatron Int'l Corp.* v. *FTC*, 884 F.2d 1489, 1498 (1st Cir. 1989).

b. In 2004, the Commission filed suit against petitioners in federal district court, alleging that many of their advertising claims about their dietary supplements were false and/or lacked a reasonable basis in scientific evidence. Pet. App. 6a-7a, 34a-35a, 49a, 53a-54a, 62a-63a. The FTC sought an injunction against future violations and repayment of nearly $16 million in revenue petitioners had earned from selling the supplements. *Id.* at 71a, 79a; see 15 U.S.C. 53(b). Following cross-motions for summary judgment, the district court granted judgment in favor of the Commission. Pet. App. 85a-86a.

The district court rejected petitioners' First Amendment challenge to the Commission's standards for determining whether an advertisement is false or deceptive. Pet. App. 21a-22a. Petitioners argued that those standards constituted an impermissible restriction on commercial speech under the test set forth in *Central Hudson Gas & Elec. Corp.* v. *Public Serv. Comm'n*, 447 U.S. 557 (1980). The district court observed, however, that the *Central Hudson* test applies only to constitutionally protected speech, and that false speech is not constitutionally protected. Pet. App. 21a-22a. The court therefore rejected petitioner's argument—"that the Court must use the *Central Hudson* test * * * to determine

whether or not speech is protected"—as a "confusing" and "illogical" exercise in "circular logic." *Id.* at 22a.

The district court also rejected petitioners' constitutional vagueness challenge to the Commission's requirement that advertising claims about dietary supplements be supported by "competent and reliable scientific evidence." Pet. App. 23a-25a. That phrase was not impermissibly vague, the district court held, because it had been defined by the Commission to mean "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *Id.* at 24a (quoting *Dietary Supplements Guide* 9). The court explained that, although the application of that "context specific" rule will necessarily vary depending on how experts would evaluate a particular type of advertising claim, "the standard by which these issues of fact are resolved is clear." *Id.* at 23a-24a.

Turning to the merits of the case, the district court determined, applying the traditional summary judgment standards, Pet. App. 12a-13a, that all but one of the advertising claims identified in the Commission's complaint violated the Act. *Id.* at 61a-62a, 65a. The court concluded that petitioners had not merely made claims about the efficacy, safety, and testing of various ingredients of their dietary supplements, but had made claims about the efficacy, safety, and testing of their dietary supplements as a whole. *Id.* at 41a ("The unambiguous intent and meaning of the advertisement is that Thermalean—not its 'proprietary components'—causes rapid and substantial weight loss."); see *id.* at 43a, 47a n.17, 55a n.19. It found no dispute of material fact that those

claims were material to consumers in deciding whether to purchase the supplements. *Id.* at 60a-61a, 64a-65a. And it found no dispute of material fact that the claims were false, unsubstantiated, or both. *Id.* at 57a-60a, 64a-65a. In making that latter determination, the district court relied on petitioners' concession that the supplements had not been scientifically tested (as various advertisements claimed that they had) and the Commission's unrebutted expert evidence that, in the absence of such testing, petitioners lacked a reasonable basis for making various claims about the supplements' efficacy and safety. *Id.* at 58a-59a.

3. The court of appeals affirmed the district court's "well-reasoned decision" in an unpublished per curiam opinion. Pet. App. 2a.

ARGUMENT

The district court correctly granted summary judgment based on the uncontroverted evidence presented by the Commission. The Eleventh Circuit's decision affirming that judgment does not conflict with any decision of this Court or any other court of appeals. Further review is not warranted.

1. Petitioners contend (Pet. 9-14) that the district court's decision violates their First Amendment right to engage in commercial speech. That contention lacks merit. The district court determined that petitioners' advertisements were false and misleading. Pet. App. 57a-60a, 64a-65a. False and misleading commercial speech does not receive First Amendment protection. See *Zauderer* v. *Ohio Office of Disciplinary Counsel*, 471 U.S. 626, 638 (1985) ("The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or mislead-

ing."); see also, *e.g.*, *Thompson* v. *Western States Med. Ctr.*, 535 U.S. 357, 367 (2002); *Virginia State Bd. of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771-772 (1976).

Contrary to petitioners' assertion (Pet. 10-11), the district court's determination that petitioners' advertisements were false and misleading does not conflict with the D.C. Circuit's decision in *Pearson* v. *Shalala*, 164 F.3d 650 (1999). That case concerned a regulation under which the Food and Drug Administration (FDA) would allow health claims to appear on a dietary supplement's label only if there were "significant scientific agreement" that the claims were true. *Id.* at 652 (quoting 21 C.F.R. 101.14(c)). The FDA had applied the regulation to ban certain health claims for which the marketers had "supporting evidence," on the ground that the supporting evidence was "inconclusive for one reason or another and thus failed to give rise to 'significant scientific agreement.'" *Id.* at 653. The court held that this regulatory approach violated the First Amendment: the health claims were protected by the First Amendment because they were only "potentially misleading," rather than "inherently misleading," (*id.* at 655); and the agency had not considered whether this problem could be cured through the less-restrictive means of adding disclaimers (*id.* at 656-657).

This case, in contrast to *Pearson*, involves marketing claims that were *actually* misleading, not just potentially misleading. See *Pearson*, 164 F.3d at 655 (recognizing that if marketing claims "could be thought inherently misleading, that would be the end of the inquiry," because the claims would not be protected speech). Unlike in *Pearson*, the district court here determined that petitioners' advertisements were "false" because, for

example, they "assert[ed] that a clinical test was performed on the products" when petitioners "admitted that the products have not been clinically tested." Pet. App. 59a; see *id.* at 60a, 64a. Also unlike in *Pearson*, the district court here determined that petitioners had made claims that they had no "reasonable basis" to believe were true, because they were unsupported by any "competent and reliable scientific evidence." *Id.* at 57a-58a; cf. *Pearson*, 164 F.3d at 653 (noting that there was "supporting evidence" for the label claims at issue). Petitioners identify no decision holding that either of these forms of speech is protected under the First Amendment.*

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* Petitioners attempt to rebut the district court's conclusion that their speech was false and misleading by asserting that the FTC "conceded in discovery that 'it did not contend that any individual statement in the advertisement was not 100% accurate.'" Pet. 8-9; see *id.* at 13. That language is taken out of context from the Commission's responses to petitioners' interrogatories. A fuller quotation demonstrates that the Commission was not admitting that petitioners' speech was truthful, but was instead making clear that its complaint was based on each advertisement viewed as a whole, rather than on isolated statements therein. 1:04-CV-3294 Docket entry No. 168-1, Exh. M at 10, 22, 30 (N.D. Ga. Aug. 24, 2007) ("[T]he Commission's allegations against [petitioner National Urological Group, Inc.] are based upon claims derived from the overall net impression that is created by the interaction of various elements in the challenged advertising * * *. Regarding how and/or why the [Commission] contends that the advertising claim departs from 100% accuracy, it is not the Commission's contention that any individual statement contained in the challenged advertisement * * * is not 100% accurate. The Commission charges [petitioners] with making claims that are false and/or unsubstantiated."); see *id.* at 7, 15, 27 ("[I]t is neither the Commission's burden nor a necessary element of the Commission's proof in this litigation to demonstrate that any individual statement * * * contained in the challenged advertisement * * * is false or misleading.").

2. Petitioners also contend (Pet. 14-16) that the Commission's "competent and reliable scientific evidence" standard is unconstitutionally vague. As a threshold matter, that contention bears only upon the district court's conclusion that certain claims were unsubstantiated (because petitioners lacked a reasonable basis for making them), and not upon its separate conclusion that many of these same claims (and others) were provably false. See Pet. App. 34a-35a, 49a, 53a-54a, 62a-63a. It therefore would not provide a basis for petitioners to avoid liability.

In any event, the district court correctly rejected petitioners' vagueness argument. As the district court recognized, and as petitioners acknowledge, the Commission has provided published guidance on how its standard applies in cases like this. Pet. App. 23a-24a; Pet. 15; see, *e.g.*, *Dietary Supplements Guide* 9-18 (explaining how the standard is "defined in [Commission] cases" and describing application of the standard, including 15 examples). Petitioners' generalized complaint that this guidance is insufficient (Pet. 15), which declines even to quote the guidance or to address it with any degree of specificity, provides no reason to disturb the district court's conclusion. Petitioners' assertion that they "cannot be expected to review the [Commission's] vague standard and have any confidence as to whether the [Commission] would consider their substantiation for their advertising claims adequate" (*ibid.*) rings hollow in a circumstance where they did not do *any* scientific testing on the dietary supplements to support their advertising claims.

Petitioners are mistaken in suggesting (Pet. 14-15) that the court in *Pearson* reached a conflicting result. That decision held (in addition to its First Amendment

holding) that the Administrative Procedure Act required the FDA to "explain what it mean[t]" by requiring claims in dietary supplement labels to be supported by "significant scientific agreement." 164 F.3d at 661. Even assuming that the court would have reached that same conclusion as a constitutional matter, see *id.* at 660 ("[c]onsideration of [the] constitutional claim seems unnecessary"), it would not dictate the outcome here. The Commission's standard here ("competent and reliable scientific evidence") shares only a single word in common with the standard addressed in *Pearson* ("significant scientific agreement"), and there is no reason to believe that the vagueness analysis would be the same. Moreover, the Commission's extensive guidance provides exactly what the court found lacking in *Pearson*: an explanation of what the agency "means by" its standard. *Id.* at 661.

3. Petitioners additionally contend (Pet. 16-20) that the district court's decision "eviscerates" the Dietary Supplement Health and Education Act of 1994 (DSHEA), Pub. L. No. 103-417, 108 Stat. 4325. That contention appeared for the first time in their appellate petition for rehearing, and it was not addressed by either the district court or the court of appeals. See Pet. for Reh'g En Banc 3, 9-11. This Court does not ordinarily consider issues that were neither pressed nor passed on below, see, *e.g.*, *Zobrest* v. *Catalina Foothills Sch. Dist.*, 509 U.S. 1, 8 (1993), and there is no reason for it to do so here.

In any event, petitioners' argument is without merit. *Inter alia*, the argument rests on the premise that petitioners' advertisements comply with DSHEA's requirement that "the manufacturer of [a] dietary supplement ha[ve] substantiation that" a statement made about the

supplement "is truthful and not misleading." DSHEA § 6, 108 Stat. 4329 (21 U.S.C. 343(r)(6)(B)); see Pet. 16-17. The district court concluded, however, that petitioners had made claims that were not truthful and not substantiated. Pet. App. 57a-60a, 64a-65a.

4. Petitioners finally contend that the district court erred by granting the Commission's motion for summary judgment because there were material facts in dispute. Pet. 21-24. That fact-bound contention does not warrant this Court's review.

The district court correctly applied the well-settled legal standard to the parties' cross-motions for summary judgment. Pet. App. 12a-13a. It considered the evidence and the arguments at length before granting the Commission's motion on the ground that no reasonable jury could find for petitioners. *Id.* at 25a-86a; Fed. R. Civ. P. 56(c)(2). The court determined that petitioners had admitted critical facts (*e.g.*, Pet. App. 59a), failed to rebut evidence presented by the Commission (*e.g.*, *id.* at 58a), and neglected to comply with local rules concerning summary judgment motions (*e.g.*, *id.* at 60a).

Petitioners do not demonstrate that the outcome would have been different in another circuit. Contrary to petitioners' assertion (Pet. 22), the D.C. Circuit does not require the Commission to present consumer survey evidence in order to prove that an advertisement is deceptive. See *FTC* v. *Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 40 (1985) ("[W]e do not accept appellant's contention that consumer survey evidence must, as a matter of law, be presented to support a finding that an advertisement has a tendency to deceive and violates section 5 of the FTC Act.") (cited at Pet. 22). Further review is accordingly unwarranted.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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SEPTEMBER 2010